DEPARTMENT OF HEALTH AND SENIOR SERVICES
OFFICE OF MANAGED CARE

Health Care Quality Act: General Implementation

Proposed Readoption with Amendments: N.J.A.C. 8:38A

Proposed New Rules: N.J.A.C. 8:38A-4.5A, 4.10A, 4.15A, 4.15B, 4.15C, 4.15D, 4.15E, 4.15F, 4.15G, 4.15H, and 4.18

Authorized By: _____
Fred M. Jacobs, M.D., J.D., Commissioner
New Jersey Department of Health and Senior Services
in consultation with Donald Bryan, Acting Commissioner
New Jersey Department of Banking and Insurance

Authority: N.J.S.A. 26:2S-1 et seq.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2005-

Submit written comments by (60 days following the date of publication) to:

Chanell McDevitt, Regulatory Officer
Office of Managed Care
New Jersey Department of Health and Senior Services
P.O. Box 360
Trenton, NJ 08625-0360
Fax: 609-633-0660

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) proposes to readopt N.J.A.C. 8:38A, which implements the provisions of the Health Care Quality Act, P.L. 1997, c. 192 (substantially codified at N.J.S.A. 26:2S-1 et seq.), and referred to herein as the HCQA. Pursuant to the provisions of N.J.S.A. 52:14B-5.1c, the rules in N.J.A.C. 8:38A are scheduled to expire on May 1, 2005. In accordance with N.J.S.A. 52:14B-5.1c, the submission of this notice of proposal to the Office of Administrative Law extends the expiration date of N.J.A.C. 8:38A 180 days to October 27, 2005.

The Department also proposes to amend the chapter, and is proposing new rules for the chapter. The purpose of the proposed amendments and new rules are explained separately below, but in general, the Department believes the proposed amendments and new rules would state with greater precision as well as amplify certain requirements of the existing rules, and would allow both the Department and the regulated community to streamline certain operations.

The HCQA establishes certain standards that must be met by various classes of carriers (insurers doing a health insurance business, hospital service corporations, medical service corporations, health service corporations as well as health maintenance organizations) offering health benefits plans in New Jersey, but is primarily focused upon carriers offering managed care plans or other health benefits plans with utilization management (UM) features. The HCQA also establishes an Independent Health Care Appeals Program (IHCAP), and requires that the Department engage in certain data gathering and reporting activities. The HCQA authorizes the Department to promulgate rules to

implement the provisions of the statute, in consultation with the Department of Banking and Insurance (DOBI). The HCQA empowers the Department to establish standards for non-HMO carriers offering managed care plans and health benefits plans with UM features that are consistent with the standards established for HMOs, as the Department believes appropriate for the types of policies and carriers involved. The Department has reviewed N.J.A.C. 8:38A and, with the exception of the amendments and proposed new rules described below, has determined the existing rules to be necessary, reasonable and proper for the purpose for which they were originally promulgated. Accordingly, the Department proposes that N.J.A.C. 8:38A be readopted with amendments, simultaneously with the proposed new rules.

In accordance with the HCQA, the Department promulgated N.J.A.C. 8:38A, with an effective date of May 1, 2000. The rules were developed in consultation with DOBI and a Department-convened task force composed of a broad cross-section of interested parties, predominantly representative of carrier and health care provider interests, but including others as well. A summary of the subchapters of N.J.A.C. 8:38A follows:

N.J.A.C. 8:38A-1 sets forth the scope and purpose of the chapter, definitions used in the chapter, and compliance timeframes that carriers must meet.

N.J.A.C. 8:38A-2 sets forth general provisions that are applicable to all carriers offering health benefits plans, as that term is defined. The subchapter includes the requirement that carriers submit a form, referred to as the HCQA

Registration Form, to the Department providing information about certain features that a carrier includes in all of the health benefits plans that the carrier intends to offer in New Jersey. The subchapter specifies certain disclosures that all carriers are required to provide to subscribers, including descriptions of cost-sharing requirements, how services may be obtained, and use of emergency response systems in New Jersey. The subchapter includes statements that, to the extent that such disclosures are contained in forms filed with DOBI (such as policy forms and marketing material), the Department will deem such forms as approved for purposes of compliance with the HCQA. The subchapter details certain rights that carriers must extend to covered persons and requires carriers to have policies and procedures in place to assure that these rights are preserved, and that covered persons are made aware of them. The subchapter establishes standards regarding emergency and urgent care services at various hospital settings. The subchapter sets forth the manner with which violations of the chapter will be dealt.

N.J.A.C. 8:38A-3 establishes standards and procedures for carriers offering health benefits plans with UM features. The subchapter sets forth additional disclosure requirements that carriers must provide to covered persons when UM features are included in health benefits plans, particularly regarding the right of the covered person to appeal adverse UM determinations made by the carrier, including the opportunity to bring the appeal to the IHCAP in the event that the covered person continues to be dissatisfied with the outcome of the carrier's determinations. The subchapter sets forth a requirement that the carrier

designate a physician licensed to practice medicine in New Jersey to serve as the carrier's medical director with respect to the carrier's health benefits plans with UM features, and specifies the minimum activities for which the medical director is to be responsible. The subchapter requires that carriers establish a UM program that has the capacity to evaluate the effectiveness of the carrier's UM features, assures that medical guidelines and protocols used by the carrier are consistent with generally accepted standards, and assures that covered persons have access to UM personnel in a reasonable manner. In addition, the subchapter requires that the UM program link into a continuous quality improvement program, which should result in revised operations, policies or procedures for the UM program as necessary or appropriate. The subchapter establishes certain standards that a carrier's internal appeal mechanism must meet in order to address appeals of covered persons (or health care providers acting on behalf of a covered person with the covered person's consent) regarding the carrier's adverse UM determinations. The subchapter specifies standards and procedures that carriers must meet in complying with decisions of the IHCAP.

N.J.A.C. 8:38A-4 sets forth provisions that are applicable to carriers offering managed care plans. Managed care plans essentially are network-based health benefits plans. The subchapter establishes additional disclosure requirements that carriers must provide to covered persons covered under a managed care plan, as well as to other consumers who might be interested in becoming covered under a managed care plan. These additional disclosures

must include such information as the general method of compensation to health care providers, lists of in-network health care providers and their respective certifications and affiliations. The subchapter sets forth a requirement that the carrier designate a physician licensed to practice medicine in New Jersey to serve as the carrier's medical director for the managed care plan's UM program, and sets forth other duties for which the medical director, or the medical director's designee, are responsible with respect to the managed care plan. These responsibilities include overseeing medical services when the managed care plan includes a gatekeeper system, provider credentialing functions, and methods by which network health care providers may have input in the carrier's medical guidelines and protocols. The subchapter requires the carrier to establish a complaint mechanism capable of addressing and resolving complaints presented by both covered persons and health care providers. The subchapter establishes standards for carriers in terms of their handling of applications from providers interested in participation in the carrier's network. The subchapter establishes standards and procedures that carriers must employ when terminating health care providers in certain circumstances, including some details about assuring that covered persons do not immediately lose access to terminating health care providers, particularly when the covered person is undergoing a course of treatment. The subchapter sets forth standards for network adequacy with respect to multiple categories of health care providers and certain health care services. The subchapter requires that carriers offering managed care plans have a UM program, including a UM appeal mechanism.

While incorporating the same provisions applicable to HMOs in N.J.A.C. 8:38-3 with respect to the standards for the UM program and UM appeal process, the subchapter also adds specific requirements regarding access by covered members to their primary care providers. The subchapter requires carriers to have a continuous quality improvement program, and incorporates substantially the provision of N.J.A.C. 8:38A-3 with respect to this subject. However, in addition, N.J.A.C. 8:38A-4 establishes standards for carriers to obtain independent evaluations of various aspects of their operations from quality review organizations. The subchapter also requires carriers to report quality outcome measures upon the request of the Department. The subchapter establishes certain standards for contracts between carriers and health care providers, whether the contracts are written directly or through an intermediary party (vendor). The subchapter sets forth certain requirements for carriers to assure that at least some of the managed care plans they make available in the market do not require a gatekeeper system.

N.J.A.C. 8:38A-5 sets forth general requirements for the IHCAP, focusing upon how the Department will operate the IHCAP.

The Department is proposing the readoption with amendments, including new rules designed to meet the following goals: (a) stating with greater precision certain provisions of the chapter that have generated questions from time to time since the rules were first promulgated; (b) bringing provisions of the chapter into greater harmony with Federal rules regarding similar subject matter that were adopted since the rules were first promulgated, so that it is easier for carriers to

comply with both Federal and State requirements; (c) bringing provisions of the chapter into greater harmony with changes in other State statutes and rules that occurred after the rules were adopted and which have a direct or indirect impact upon the operation of the chapter, so compliance issues will be less confusing for the regulated industry; (d) revising certain provisions of the chapter, to make more explicit certain of the standards against which the Department has measured carrier compliance since the promulgation of the rules; some of these proposed revisions have been captured and stated in bulletins issued by the Department in recent years as a means of providing further guidance to carriers or others; (e) eliminating those provisions that are no longer necessary or practical in the current regulatory environment or marketplace; and, (f) correcting inaccuracies within the rules. A summary of the proposed amendments and new rules follows:

The Department is proposing to amend the title of N.J.A.C. 8:38A from "Health Care Quality Act Application to Insurance Companies, Health Service Corporations, Hospital Service Corporations and Medical Service Corporations" to "Health Care Quality Act: General Implementation for Insurance Companies, Health Service Corporations, Hospital Service Corporations and Medical Service Corporations." The proposed change recognizes the Department's creation of N.J.A.C. 8:38C, which also contains rules interpreting provisions of the HCQA. The rules contained in N.J.A.C. 8:38C interpret subsequent amendments made to the HCQA that, thus far, apply only to carriers offering managed care plans. However, N.J.A.C. 8:38A and 8:38C both establish rules applicable to carriers

and implementing the HCQA. The rules at N.J.A.C. 8:38A are general in nature, while the rules at N.J.A.C. 8:38C cover very specific topics and apply to HMOs as well as the carriers subject to N.J.A.C. 8:38A.

At N.J.A.C. 8:38A-1.2, the Department is proposing to amend certain definitions, and add new definitions. The Department is proposing to amend the current definitions of ”health benefits plan,” “Independent Health Care Appeals Program,” “Independent utilization review organization,” “Provider,” and “Secondary contractor.” The Department is proposing to add the following definitions: “Adverse determination,” “Continuity of care period,” “Credentialing,” “Dental benefits plan,” “Health care facility,” “Management agreement,” “Medical necessity,” and “Organized Delivery System.”

The Department is proposing to add the term “Adverse determination” to the chapter definitions to describe those UM determinations made by a carrier that can be appealed by a covered person. Use of this new term would make the rules read more consistently with Federal rules promulgated by the United States Department of Labor at 29 C.F.R. 2560.503, which use the term “adverse determination” to describe certain types of actions that can be appealed by individuals covered under group health plans that are subject to Federal law. There is some overlap in jurisdiction between the State and Federal laws with respect to certain types of health benefits plans and the rights of individuals to appeal certain types of coverage decisions made by the sponsors or administrators of the health benefits plans. Although the State is not required to follow the federal rules regarding UM appeals, the Department recognizes that

the compliance burden for the regulated industry would be reduced if there is greater consistency between the state and federal requirements, and that consistency would make the appeal systems less confusing for all parties, including the Department. The definition proposed is identical to the federal definition.

The Department is proposing to add the term “Continuity of care period” to the chapter definitions to describe the period of time following the termination of a provider agreement during which the carrier and health care provider must continue to allow covered persons to access the services of the health care provider subject to the terms of the terminated provider agreement. The Department is proposing to add the term because the Department is amending existing rules regarding the continuity of care period (increasing substantially the level of detail regarding actions that should and should not occur during the continuity of care period). The Department believes that the increased discussion warrants addition of the term to the chapter.

The Department is proposing to add the term “Credentialing” to the chapter definitions to specify the process that carriers are required to employ to verify the qualifications of health care professionals. The Department is proposing new rules addressing the credentialing function, and the term arises in that context and therefore requires definition.

The Department is proposing to amend the current definition of “Health benefits plan” in part for grammatical purposes, and in part to make explicit that the term applies to health insurance policies providing coverage for

both limited as well as more comprehensive sets of services. The term is set forth in the HCQA, where it is defined as a policy that contains benefits for hospital and medical expenses. The use of the word "and" has always begged the question of whether only those policies and contracts that contain coverage for both hospital and medical expenses or a broader class of policies (offering limited services) are subject to the HCQA. Initially, the Department considered the HCQA applicable only to policies that included both hospital and medical expense coverage, despite certain statutory definitional inconsistencies in this regard. However, subsequently-enacted legislation referencing the HCQA indicates that the Legislature did not mean to limit the HCQA to such policies. Because the first piece of legislation indicating this, L. 1999, c. 409 (codified as N.J.S.A. 17:48H-1 et seq., establishing licensing or certification requirements for Organized Delivery Systems), was enacted in January of 2000, the Department has operated under the premise of broader applicability for some time, but did not revise the definition contained in the rules to reflect this broader interpretation. However, the Department now believes it appropriate to make this interpretation explicit. The Department believes this will better demonstrate the harmony in the interaction between the HCQA, the Organized Delivery Systems statute, the so-called Right-to-Sue law (L. 2001, c. 187) and the Domestic Partnership Act (L. 2003, c. 246).

The Department is proposing to add the term "Health care facility" to the chapter definitions for sake of clarity when subcategories of the term "provider" are used throughout the chapter. The definition references the provisions of

N.J.S.A. 2H-1 et seq., which governs the establishment and licensure of health care facilities.

The Department is proposing to add the term “Health care professional” to the chapter definitions for sake of clarity when subcategories of the term “provider” are used throughout the chapter. The proposed definition includes licensed or certified individuals (natural persons) who provide health care services and whose scope of practice is regulated by Title 45 of the New Jersey Statutes.

The Department is proposing to amend the existing term “Independent Health Care Appeals Program” to add the acronym “IHCAP,” and to further specify the types of appeals that are subject to the IHCAP. The proposed amendment would codify guidance provided to carriers several years ago via Bulletin 2000-03, Bulletin 2000-04 and Bulletin 2001-02, addressing UM appeals among other subjects. The additional language would make it explicit that the IHCAP may entertain appeals of denials for otherwise covered services when the carrier’s basis for denial is that the service is cosmetic, not medical in nature, or that it is experimental or investigational for the case at hand.

The Department is proposing to amend the existing term “Independent utilization review organization” or “IURO” in order to better describe the composition of an entity that could be an independent review organization. The Department is proposing the amendment to help assure readers of the independent nature of the review organizations that the Department contracts with for performance of review functions under the IHCAP, as well as provide

increased guidance for those parties that may be interested in becoming a designated IURO.

The Department is proposing to add the terms “Management agreement” and “Service agreement” to the chapter definitions. The Department has used the term “management agreement” internally for several years to describe the types of contracts existing between carriers and secondary contractors for the provision of health care services, as well as contracts with vendors for the provision of certain administrative services indirectly related to the provision of health care. However, the Department had not defined management agreement. (The Department notes that the Department’s use of the term “management agreement” is not consistent with DOBI’s use of the term, which is defined for that agency in connection with the Holding Company Act, N.J.S.A. 17:27A-1 et seq., and rules at N.J.A.C.11:1-35.) With the promulgation of the Organized Delivery Systems (ODS) rules at N.J.A.C. 8:38B, the Department determined it was appropriate to define management agreement in order to distinguish the two types of contracts governed by the rules at N.J.A.C. 8:38B, with management agreement being the name given to those contracts between carriers and ODSs, and provider agreement being the name given to those contracts between ODSs and health care providers for the provision of health care services to a carrier’s membership. As defined at N.J.A.C. 8:38B-1.2, the term “management agreement” refers to a narrower class of contracts in comparison with the Department’s common usage of the term. In an effort to try to maintain consistency among the various rules regulating some aspect of managed care,

the Department is proposing to define management agreement at N.J.A.C. 8:38A-1.2 the same as the Department has defined the management agreement at N.J.A.C. 8:38B-1.2. Consequently, the Department also is proposing an additional term encompassing those contracts between carriers and organizations for the performance of certain delegated functions that are indirectly related to the provision of health care services for a carrier's membership (and thus, not subject to N.J.A.C. 8:38B). The Department believes that inclusion of these two new terms would help to explain when carriers and their subcontractors need to comply with provisions of the HCQA rules as well as the ODS rules.

The Department is proposing to add the term "medical necessity" or "medically necessary" to the chapter definitions. Health care providers have been requesting a definition of these terms for some years, apparently in the hope that such a definition might reduce UM disputes. The proposed definition states that a treatment or service is considered medically necessary when it is appropriate and consistent with a patient's diagnosis and that its omission would, in accordance with accepted standards of practice, adversely affect the patient's condition or quality of care. In proposing this definition, the Department recognizes that accepted standards of practice are dynamic, and can and should change over time, and that these standards are not always or necessarily articulated in one place or in writing.

The Department is proposing to add the term "Organized Delivery System" or "ODS" to the chapter definitions. ODSs are now entities directly regulated in

New Jersey through the Department and/or DOBI. Most carriers contract with ODSs in order to have a network for the carrier's managed care plans. The Department is proposing the addition of the term and definition because of use of the term throughout the chapter and cross-references to rules at N.J.A.C. 8:38B regulating ODSs. This term is defined in the same way as in existing N.J.A.C. 8:38B-1.2.

The Department is proposing to amend the existing definition of "Provider" to reflect the proposed definitions of the two major categories of health care providers, health care professionals and health care facilities. The primary reason for making a distinction between the two types of providers is that some rules in the HCQA only apply with respect to certain classes of providers, while other rules apply more universally across providers. Thus, the Department anticipates that refining the definition will help to provide better guidance to carriers and other interested parties.

The Department is proposing to amend the existing definition of "Secondary contractor" to provide a list of the types of entities that may serve as secondary contractors (intermediary contractors), including carriers, HMOs, dental service corporations, dental plan organizations, fraternal benefit societies or ODSs. The Department is deleting reference to the possibility of a so-called primary contractor also being a secondary contractor when acting akin to a broker for health care services. Although a primary contractor can still be a secondary contractor, a primary contractor in that instance would more appropriately be referred to as an ODS. The Department believes retention of

the older, descriptive language would be confusing given the newer terminology set forth by statute, and thus, the Department considers deletion of the older language to be prudent.

At N.J.A.C. 8:38A-1.3, setting forth compliance timeframes, the Department is proposing to amend the rule to establish when carriers are expected to bring their existing provider agreements, management agreements and service agreements into compliance with all applicable changes in the rules. The Department is proposing to permit carriers up to a year to come into compliance.

At N.J.A.C. 8:38A-2.2, the Department is proposing to amend the rule to remove reference to DOBI, because DOBI has indicated that it does not need a copy of the HCQA Registration forms filed with the Department.

At N.J.A.C. 8:38A-2.3, the Department is proposing to amend the rule to specify a date (May 1, 2000), in lieu of the language “operative date of the rules.” The proposed amendment would correct a printing error. In addition, the Department is proposing to substitute the word “have” for “has” at N.J.A.C. 8:38A-2.3(a)4ii to correct a grammatical error.

At N.J.A.C. 8:38A-2.5, regarding the rights of covered persons, the Department is proposing to make a grammatical change only, amending the term “person” to read as “persons.”

At N.J.A.C. 8:38A-2.6, regarding emergency and urgent care services, the Department is proposing multiple changes. At N.J.A.C. 8:38A-2.6(a)1, the Department is adding language to point out that all transfers from a trauma

center to other hospital facilities are subject to Federal and State rules applicable to hospitals and governing such matters. While the hospitals' obligation is clear under Federal and state hospital rules, the Department believes it would be useful to point out in rules governing carriers that they must not request transfer of a covered person in contravention of the rules governing hospitals. At N.J.A.C. 8:38A-2.6(a)2, the Department is proposing to require carriers to consider a hospital as in-network for purposes of benefits to the covered person if the carrier becomes aware that the covered person could be transferred, and the carrier elects not to pursue the transfer. The Department is proposing this language so that the hospital and the covered person would not be penalized for the carrier's inaction. At N.J.A.C. 8:38B-2.6(b), the Department is adding language throughout the section to further address standards regarding medical screening requirements and reimbursements for medical screenings in hospital emergency departments. This language is based on guidance previously provided by the Department through Bulletin 2003-04 and is in response to frequent disputes that providers and/or carriers have brought to the Department's attention as to what must be covered as part of a medical screening. The proposed new language at N.J.A.C. 8:38A 2.6(b)1 and 2 indicates that the covered medical screening in a hospital emergency department must comply with hospital licensure standards at N.J.A.C. 8:43G-12.6 and 12.7. Proposed N.J.A.C. 8:38A 2.6(b)3 states that the proposed new language would not prevent hospitals and carriers from negotiating predetermined medical screening rates, and proposed N.J.A.C. 8:38A-2.6(b)4 indicates the proposed new language

would not prevent carriers from applying cost-sharing requirements to covered persons.

At N.J.A.C. 8:38A-3.2, regarding disclosure requirements for those carriers offering health benefits plans with UM features, the Department is proposing to amend the rule to reflect that determinations rendered through the IHCAP are binding upon carriers. This change is required as a result of legislative action occurring in 2001 (L. 2001, c. 1), and would make the rules consistent with the statute and current practice.

At N.J.A.C. 8:38A-3.3, which pertains to designation of a medical director, the Department is proposing to add language to indicate that carriers may designate a dentist to serve in the capacity of "medical director" for health benefits plans that provide dental only coverage (that is, dental benefits plans). The amendment is consistent with the statute at N.J.S.A. 26:2S-6(b)1, which states that adverse utilization management decisions are to be made by a physician except in the instance in which the services at issue are prescribed by a dentist, in which instance, the utilization management decision may be made by a dentist. The language is also consistent with the Department's current practice in reviewing the utilization management programs of carriers for dental services. In addition, the Department is proposing language that would permit carriers offering limited benefits plans that cover services not performed by physicians and/or surgeons, to designate a health care professional licensed in New Jersey to perform the services that are covered under the limited health benefits plan. The Department believes this proposed language would help to

assure that the most appropriately trained professionals will have oversight of the services and protocols covered under the policies being offered. So, for instance, carriers offering limited benefits plans covering alternative medicines could appoint a licensed practitioner of the alternative medicine as the medical director for the UM program, rather than a physician who may not be familiar with the alternative medicine at issue, or the associated best practices.

At N.J.A.C. 8:38A-3.4(a), which pertains to utilization management, the Department is proposing language to state that certain requirements of the rule would apply with respect to health benefits plans, so that by extension they do not apply to dental benefits plans. Carriers may elect to comply with the standards for all of their products, but are only required to comply with the standards in regards to those of their health benefits plans offered with UM features. The proposed language would be an explicit expression of current oversight practice. In addition, the Department is proposing language allowing individuals other than physicians to act in the stead of the medical director for limited health benefits plans, in order to be consistent with the proposed language at N.J.A.C. 8:38A-3.2(a)1 and 2.

At N.J.A.C. 8:38A-3.4(b) through (d) and (f), pertaining to UM, the Department is proposing language changes and additions that would clarify certain standards in the rules (for instance, referencing the ability of a dentist to make UM determinations when the situation involves dental services), and provide more explicit standards with respect to qualified UM personnel availability and general access to UM services by covered persons and their health care

providers, disclosures about the ability to appeal UM determinations, as well as policies and procedures used to make UM determinations. In addition, the Department is proposing language intended to bring the rules into closer alignment with Federal standards at 29 C.F.R. 2560.503 regarding the ability of individuals covered under group health plans to appeal adverse determinations, and the timeframes specified under Federal law for issuing a decision on an appeal, and providing specific information regarding what the carrier relied upon in arriving at its decision on the specific appeal.

At N.J.A.C. 8:38A-3.5, setting forth the requirements for a carrier's internal UM appeals process, and standards thereof, the Department is proposing numerous changes throughout to bring the rules into greater alignment with Federal rules at 29 C.F.R. 2560.503 governing similar processes for employment-based group health plans. Specifically, the Department is proposing an amendment that would prohibit carriers from requesting evidence of specific consent from a provider appealing on behalf of a patient in situations controlled by the federal rules (in essence, appeals made by an attending physician in urgent care situations – as urgent care is defined by the federal rules). The Department is also proposing the Federally-prescribed minimum 180-day period following an adverse determination in which covered persons may file an appeal. The Department is proposing that the reviewer at Stage 1 *not* be the same physician that made the initial adverse determination, consistent with Federal regulations. The Department is proposing to incorporate the concepts of pre-service and post-service adverse determinations and allowing carriers a longer

time in which to render decisions on post-service adverse determinations, as is permitted by the Federal regulations. The Department anticipates that these proposed changes would make it easier for carriers to comply with both State and Federal standards, and would allow carriers to streamline some of their operations.

In addition, the Department is proposing some language changes at N.J.A.C. 8:38A-3.5 not prompted by the Federal regulations, but which the Department believes will reduce areas of confusion that currently exist. For instance, the Department is proposing more explanatory language about the rule's requirements in Stage 2 of the internal appeal process regarding composition of health care provider panels and when consultant physicians should be used; the Department is proposing language regarding the use of specific consent forms by carriers, and what types of informational requirements in the consent forms the Department considers reasonable and unreasonable; and, the Department is proposing language providing more detail regarding the notice requirements with which carriers' correspondences with covered persons and health care providers about the appeal process and the specific appeal must comply.

At N.J.A.C. 8:38A-3.6, regarding the IHCAP, the Department is proposing changes to address confusion as to the application of the existing rules, and to make certain grammatical or cross-references changes necessitated by other proposed changes elsewhere. At N.J.A.C. 8:38A-3.6(a), the Department is adding language to make it clear that consent allowing a health care provider to

appeal on behalf of a covered person must be specific to the appeal, and not a general consent provided for the receipt of services upon admission to a health care facility or prior to the initiation of services by a health care professional. This language change would make the Department's current practice more explicit. Hospitals have urged the Department to permit use of a general consent statement secured in advance of any UM denial, arguing that it is often difficult to contact a patient and secure a specific consent after a denial, particularly when the adverse UM decision entails adverse economic consequences only for the hospital and not the patient. While the Department is sympathetic to this argument it nevertheless believes it is more important to protect the covered person's right to determine whether a specific UM determination should be appealed, particularly when it involves potential appeal to the IHCAP and provision of protected health information to outside parties. Because hospital patients typically sign a number of general consents upon admission, the Department is concerned whether a general consent to appeal can be made on a fully informed basis, absent an already-rendered adverse UM decision by a carrier. In addition, the Department is proposing to revise the timeframe references for bypassing a carrier's internal appeal processes, to assure that all timeframes are consistent with Federal standards.

At N.J.A.C. 8:38A-3.6(b), the Department is proposing new language to specify that carriers must include an IHCAP application with all adverse Stage 2 denial letters or upon request when appropriate; this would make explicit current Department expectations. In addition, the Department is proposing to delete

reference to the IHCAP application form being in the appendix to the chapter (and is proposing to delete Exhibit 1, which contains the application as well), while adding language advising carriers that they may obtain the IHCAP application in electronic or paper format from the Department. When the Department originally put the form in the appendix to the Chapter, the Department did not anticipate that other parties, such as providers, would make use of the form; however, that occurred. The form is meant to be provided to covered persons by the carrier at the conclusion of a Stage 2 UM appeal; compliance is an affirmative obligation upon the carrier. (If a carrier fails to comply with that requirement, then it is an issue for the Department to address.) Because of this, when the Department began creating electronic forms and making them available on the Department's website, the Department elected not to include the IHCAP application, having reconsidered its position on general accessibility to the form. Consequently, the Department is now proposing to clarify that access to the form is limited, and to remove the form from the Chapter's appendix.

At N.J.A.C. 8:38A-3.6(c), the Department is proposing changes to reflect revisions to the list of assistance programs under the Department of Human Services that qualify a participant in these programs for reduced IHCAP fees, in an effort to keep pace with program changes and expansions. At N.J.A.C. 8:38A-3.6(d) and (e), the Department is proposing amendments articulating certain criteria that applicants for the IHCAP must meet in order for the Department to process the application and refer the case to one of the

Department's IHCAP contractors. The Department is proposing these amendments to make explicit the Department's current practices limiting the scope of appeals eligible for review through the IHCAP, based upon the Department's interpretation of the HCQA, as well as Federal laws, including the Employee Retirement Income Security Act (ERISA), 29 U.S.C. 1001 et seq., and Medicare-related statutes, 42 U.S.C. 1395 et seq. The Department's interpretation of these various laws is that the IHCAP has no jurisdiction over appeals involving self-funded plans, health benefits plans delivered in other states, or Medicare (neither traditional Medicare, Medicare+Choice policies nor Medicare Advantage policies). At N.J.A.C. 8:38A-3.6(h) through (k), the Department is proposing amendments to reflect the statutory change to the IHCAP set forth by New Jersey L. 2001, c. 1, making the determinations rendered through the IHCAP binding upon carriers. In addition, the Department is proposing amendments to further articulate standards that must be met by independent utilization review organizations (IUROs) contracting with the Department to perform proposed IHCAP functions. For the most part, the proposed standards for IURO contractors are reflective of the standards set forth in the Department's Request for Proposals (RFPs) and subsequent contracts with IUROs. However, of note, the Department is proposing to amend the rules (as well as the standards set forth in the RFP) to permit IURO reviewers to be licensed to practice in jurisdictions other than New Jersey. The Department anticipates that this amendment would encourage a broader field of IURO

applicants responding to the Department's RFPs in the future, and a more competitive contracting environment.

The Department is proposing amendments to N.J.A.C. 8:38A-3.7, regarding carrier responses to IURO decisions. The Department is proposing language changes to reflect the 2001 statutory revisions making the IHCAP decision binding, and eliminating the option for carriers to accept or reject the determination of the IURO. Additionally, the Department is proposing language that would require carriers to comply as expeditiously as possible with decisions overturning a carrier's position. The Department has received complaints in the past alleging that, absent such a requirement, carriers have been quite slow to comply with the IHCAP decision in some cases.

At N.J.A.C. 8:38A-3.8, the Department is proposing to eliminate cross references to N.J.A.C. 11:4-37 (Selective Contracting Arrangements), and add language substantially parroting sections of the DOBI rules instead. The Department believes this will help eliminate some confusion about whether carriers are required to comply with both sets of rules with respect to certain topics (such as continuous quality improvement, which N.J.A.C. 8:38A-3.8 addresses). It should be noted that the Department has never intended to duplicate review efforts with DOBI regarding carriers seeking to offer selective contracting arrangements, and this continues to be true. The proposed amendments would better reflect the actual division of review responsibilities between the Department and DOBI. The Department anticipates that DOBI may be amending the rules at N.J.A.C. 11:4-37 to further reflect the agency divisions

in responsibilities with respect to selective contracting arrangements, and coordinate their rules more closely with the rules regulating ODSs, as well as the rules contained within N.J.A.C. 8:38A.

At N.J.A.C. 8:38A-4.2, regarding disclosures to covered persons, the Department is proposing to amend N.J.A.C. 8:38A-4.2(e), repealing certain language while adding other language. The Department is proposing to repeal the requirement that carriers provide covered persons with prior notice of termination of a health care provider because the Department does not believe the requirement is appropriately placed in the rules. The notice requirements of N.J.A.C. 8:38A-4.2 are general in nature, typically will be provided around the time that the covered person obtains coverage, and typically will be provided through a handbook, certificate or other evidence of coverage. The existing language at N.J.A.C. 8:38A-4.2(e) regarding termination is not consistent with the other notice requirements, inasmuch as it is the type of notice that is circumstantial in nature and really isn't worthwhile for inclusion in a document of general information. Further, the requirement is more-or-less repeated at N.J.A.C. 8:38A-4.8(c), and dealt with in a more appropriate context there. The Department is proposing new language for N.J.A.C. 8:38A-4.2(e) that is more appropriate for a document containing generalized information, and information that a covered person should be given around the date that coverage begins. The new language would address the requirement for carriers to advise covered persons that they have the right to choose among participating primary care and specialist providers, as well as the right to assistance in being referred to

providers with experience treating patients with chronic disabilities, including non-participating providers when participating network providers are not available in a timely manner. Finally, carriers would be required to advise covered persons of their right to be free of balance-billing by participating providers for covered services that are appropriately authorized. The proposed new language corresponds with current requirements for HMOs found at N.J.A.C. 8:38-9.1, and the Department's policy with respect to non-HMO carriers offering managed care plans.

At N.J.A.C. 8:38A-4.5, addressing the responsibilities of the medical director with respect to managed care plans, the Department is proposing amendments repealing certain language regarding the credentialing committee in favor of language contained in a proposed new rule on the subject at N.J.A.C. 8:38A-4.5A, discussed more below. In addition, the Department is proposing new language that would make it an explicit requirement that carriers must be able to demonstrate active oversight by the medical director of those committees and activities for which the medical director is responsible. Under the current rules the Department has viewed active oversight as implicit in the medical director's responsibilities, but enforcement experience suggests an explicit statement of this expectation is warranted.

The Department is proposing new rules at N.J.A.C. 8:38A-4.5A regarding a carrier's credentialing committee. The proposed new rules go beyond the standards that currently exist for the credentialing committee and medical director at N.J.A.C. 8:38A-4.5, and cross reference to N.J.A.C. 8:38C-1. N.J.A.C.

8:38C-1, adopted in December of 2003, sets forth universal standards with which carriers must comply and permissible alternative procedures that carriers may implement with respect to provider participation and credentialing practices. The proposed new language would explicitly require participation of the medical director in the credentialing committee, and also would require the committee to oversee mechanisms designed to verify and periodically review provider credentials. The existing language is not as clear with respect to periodic reviews, nor does it state explicitly that the credentials of providers performing UM must be verified and periodically reviewed. The Department believes it is reasonable to expect providers that the carrier relies upon to perform UM functions will credentialed in a similar manner as are the carrier's participating network providers who deliver hands-on health care services. The proposed new language also would explicitly require a linkage between the continuous quality improvement and complaints programs and the credentialing programs. Although such linkages appear to the Department to be inherent in any well-performing credentialing program, oversight experience has demonstrated that not all carriers have established such linkages, and that an explicit requirement is necessary to promote a sound credentialing (and continuous quality improvement) program. Finally, whereas the current language simply calls for the committee to review the credentials of providers not meeting the carrier's standard requirements, the proposed new language would permit the committee to credential a provider as a primary care provider (PCP) who does not conform to the proposed amended qualifications for a PCP found at N.J.A.C. 8:38A-

4.10(f). Under the proposed new language, providers would always have to meet the carrier's credentialing standards, and the language would link the credentialing committee functions to the PCP flexibility provided under proposed N.J.A.C. 8:38A-4.10(f).

At N.J.A.C. 8:38A-4.6, the Department is proposing new language enhancing the standards for carriers' complaint programs, taking into specific consideration the necessity for carriers to resolve complaints in a timely manner, and to link their complaint resolution process into the continuous quality improvement program. The Department is proposing these amendments because the Department believes that the resulting programmatic and operational changes will be beneficial to multiple interested parties and the health care delivery system in general.

At N.J.A.C. 8:38A-4.7, the Department is proposing to amend the rules so that the standards and procedures contained in the rules would apply only with respect to network participation of health care professionals, not providers generally. The provisions of the existing rule were intended to apply only to health care professionals, not to health care facilities also; the substitution of the term "health care professional" for "provider" would make the Department's intent more explicit. The proposed amendments would also clarify that carriers may combine or separate their participation and credentialing committees, taking into consideration the conditions that work best for the carrier. In addition, the Department is proposing some grammatical corrections or clarifications.

At N.J.A.C. 8:38A-4.8, regarding termination of health care professionals from a carrier's network(s), the Department is proposing multiple amendments. The Department is proposing new procedures at subsection (a) for carriers to follow with respect to the notices provided to health care professionals. In essence, carriers would be required to always specify a reason for the termination in the notice, rather than upon request of the health care professional, as is currently permitted. In addition, carriers would be required to send notices of termination, and the reasons therefor via certified mail to all addresses on record with the carrier for the health care professional. Although more cumbersome for carriers, the Department believes that the proposed procedural changes ultimately will benefit both health care professionals and carriers, by providing guidance with respect to the type of notice that is necessary.

The Department is proposing language in subsection (c), regarding when carriers must give notice to covered persons of termination of a health care professional; the language is similar to that of N.J.S.A. 26:2S-9.1, enacted after these rules were adopted. In addition, the Department is proposing language at subsection (c) to provide more detailed requirements for the information that a notice to covered persons must or may convey, as appropriate. The Department is proposing at subsection (e) to require carriers to send a notice to terminating health care professionals of any obligations the health care professionals may have to provide services pursuant to statutory or contractual continuity of care requirements. The Department believes that these latter two requirements will

be helpful to covered persons and health care professionals alike, so that they may better understand their rights and obligations when a termination occurs.

The Department is proposing numerous amendments to N.J.A.C. 8:38A-4.10, regarding network adequacy for managed care plans. At subsection (a), the Department is removing the language setting forth an exception for compliance by certain selective contracting arrangements in existence prior to May 1, 2000, because it is no longer necessary. Selective contracting arrangements currently must be renewed periodically in order to continue in effect. All selective contracting arrangements approved prior to May 1, 2000 should have since renewed and come into compliance with N.J.A.C. 8:38A, or ceased to offer a managed care plan. At subsection (b), the Department is proposing to add language to state that, not only must carriers assure that covered persons have access to participating providers (so that covered persons may take advantage of in-network benefits), but carriers must also affirmatively provide assistance to covered persons in locating participating providers, or consider the covered person to be accessing in-network services if no participating providers are available given the medical circumstances of the covered person. The Department is proposing this language to make it explicit that carriers have an obligation not only to assure that a network exists, but to assure that covered persons have access to providers in the network, facilitating access for covered persons when necessary. The Department's position, which is reflected in the proposed amendments, is that if the carrier does not facilitate such access when necessary or appropriate, then the carrier should not be able

to penalize a covered person who subsequently seeks medically necessary care out-of-network by withholding network-based coverage due to use of an out-of-network provider.

The Department is proposing language changes throughout N.J.A.C. 8:38A-4.10(b) through (f) to strengthen the network adequacy standards applicable for primary care physicians, specialists, hospitals and other health care facility providers. Among other things, the Department is proposing language to require carriers to demonstrate access for their covered persons through assurances that health care providers are available for all age groups, are actually accepting new patients, that provider offices actually have office hours to see patients, and that provider offices are not merely administrative facilities. Over the years the Department has received numerous complaints about gaps between the appearance and the reality of carrier networks. The proposed language is intended to narrow such gaps where they exist. In addition, the Department is proposing that carriers demonstrate network adequacy assuming enrollment for a 12-month period. The Department proposes to increase the specific minimum standards for certain health care facility services. For instance, the Department is proposing that carriers have at least three skilled nursing facilities within appropriate geographic locations, in recognition of the increasing need for skilled nursing facility access by a population advancing in age, as well as frequent hospital complaints that insufficient skilled nursing capacity in carrier networks increases the difficulty in discharging covered persons in a timely, appropriate manner. The Department is

also proposing that carriers include in their networks hospitals offering tertiary services to adults, adolescents and younger children, who may require more specialized treatment. On the other hand, the Department is proposing to eliminate nurse practitioners and physician assistants from the list of practitioners eligible to be considered as primary care providers. Use by carriers of the list of other possible primary care providers has always been permissive, not mandatory. Because the Department is not aware of any carrier allowing the categories of health care providers proposed to be eliminated to act as primary care providers, the Department is under the impression that the need for this level of flexibility in designating primary care providers is not warranted. Thus, the Department does not believe there is a reason to retain all of the categories of health care providers eligible to be considered primary care providers, nor does the Department believe the proposed changes will substantially alter the actual composition of any carrier's network.

The Department is proposing a new rule at N.J.A.C. 8:38A-4.10A regarding access by covered persons to physician services after office hours. The Department is proposing the new rule to indicate the standards that the Department expects carriers to meet with respect to the provision of emergency and urgent care, while also making it clear that some flexibility in arrangements for after-hour care is acceptable in meeting the minimum standards. The Department is proposing that carriers assure that after hours services are available, but is allowing carriers and providers to come to certain agreements about the use of back-up physicians and/or triage services (not answering

services) as methods for providing services or appropriate referrals for care when a physician's office is closed and the physician is not otherwise available. The Department believes that the proposed amendments would help to make carriers more accountable with respect to both their covered persons' use of emergency departments at hospitals and the appropriate referral of covered persons to an emergency department by a physician or triage service after hours. (Referral of covered persons by physicians and triage services to the hospital emergency department outside of regular physician office hours should never occur solely as a matter of convenience, and should always be discouraged, unless a true emergency is believed to exist or be likely.) The Department also believes that the proposed amendment would help promote a better understanding of the services that are required to be covered with respect to emergency department medical screenings, without being unduly prescriptive. Medical screenings and medical screening fees have proven to be a particularly contentious issue among and between hospitals and carriers, apparently fueled by lack of full understanding by both parties as to the State and Federal requirements for medical screenings, triage and treatment of an emergency condition by hospitals.

The Department is proposing to amend N.J.A.C. 8:38A-4.11, regarding the carrier's UM program. The Department is proposing to eliminate the existing language suggesting that health benefits plans need not provide for emergency or urgent care services in some instances. While the Department continues to recognize that there may be certain limited service health benefits plans providing services that never arise on an emergency basis, and in those

instances, it is neither practical nor cost effective for carriers to try to comply with the emergency or urgent care standards, the Department is proposing more explicit language regarding this concept at proposed new rule N.J.A.C. 8:38A-4.18, which is discussed more below. The Department believes elimination of the less explicit language of N.J.A.C. 8:38A-4.11, along with the more explicit language of the proposed new rules would help to reduce confusion about the issue. With respect to health benefits plans generally, the Department is proposing to require carriers to assure that covered persons have access to UM services in the event that the covered person is not able to access his or her primary care provider or the primary care provider's back-up provider. Once again, the Department is proposing language that would emphasize the carrier's obligation to cover a medical screening. The Department believes that the proposed language would make the carrier more accountable to covered persons for access to appropriate services and in-network benefits.

At N.J.A.C. 8:38A-4.13, concerning standards for continuous quality improvement programs related to managed care plans, the Department is proposing to amend the rules, to state that carriers are required to submit a report from an external quality review organization, to specify those external quality review organizations that the Department currently recognizes, and to clarify that the Department is willing to consider other organizations when appropriate. The proposed language would be consistent with current Department standards and practice, and hopefully would reduce carrier questions to the Department about this issue. In addition, the Department is

proposing to eliminate language regarding the Healthcare Data Committee (HeDaC). The HeDaC is not a statutory creation, but rather, was created by the Department ad hoc to address data collection issues. While quite active at one time, the HeDaC has not met for several years now. The Department does not foresee any current purpose in retaining the HeDaC through regulation, and thus, is proposing to eliminate the language regarding it. In the event that the Department may have need of a similar type of committee in the future, the Department may re-constitute a new task force ad hoc.

At N.J.A.C. 8:38A-4.14, regarding provider input into protocols used by carriers in making UM determinations, the Department is proposing to amend the current rules to expand the acceptable categories of participating providers by which carriers may satisfy the input requirements. The Department believes that the proposed amendment will allow multi-state carriers greater flexibility in satisfying the regulation, and that this flexibility is reasonable, because generally accepted protocols are unlikely to vary significantly from state to state simply as a function of geography. In addition, the Department is proposing to eliminate subsection (d) regarding proprietary and quantitative thresholds as a basis for not providing clinical protocols. Carriers and health care providers argued over the meaning, and the language resulted in some carriers refusing to provide virtually any requested information. Although the provision appears not to be as much of a problem as it once was (especially with an increasing number of carriers and vendors providing electronic access to protocols for participating providers), the

Department believes that elimination of the language would make carriers more accountable to their covered persons and health care providers alike.

The Department is proposing to restructure N.J.A.C. 8:38A-4.15, regarding provider agreements, while proposing to add seven new rules, N.J.A.C. 8:38A-4.15A through 15G, addressing contract issues between carriers and health care providers, as well as certain vendors. These proposed changes are prompted primarily by the adoption of rules governing Organized Delivery Systems at N.J.A.C. 8:38B, and the need to harmonize rules between and among N.J.A.C. 8:38A and 8:38B. In developing N.J.A.C. 8:38B the Department incorporated both lessons learned in implementing N.J.A.C. 8:38 and N.J.A.C. 8:38A, as well as provider and carrier feedback. The Department believes it is necessary now to make the older rules consistent with the newer ones. The Department proposes to eliminate virtually all of the current language of N.J.A.C. 8:38A-4.15, and replace it with proposed new general language that would explain when a contract for the delivery of health care services should be complying with provisions of N.J.A.C. 8:38A and when such contracts should be complying with provisions of N.J.A.C. 8:38B. Similarly, the Department is proposing a new rule at N.J.A.C. 8:38A-4.15A that would explain when a contract characterized as a management agreement or service agreement should comply with provisions of N.J.A.C. 8:38B, and such contracts should comply with other rules governing specific subject matter. The Department anticipates that these proposed amendments and new rules will provide appropriate guidance to carriers in bringing various types of contracts for health care services into

compliance with the regulatory requirements of New Jersey, and help carriers to understand how the various sets of rules interact without duplicating one another.

The Department is proposing a new rule at N.J.A.C. 8:38A-4.15B setting forth the procedures for submission, review and approval of provider agreements and management agreements. The proposed procedures are more specific than those currently set forth at N.J.A.C. 8:38A-4.15, but also provide for a streamlined submission and review process that the Department believes will be beneficial to carriers and their contractors, at least with respect to provider agreements. Pursuant to the proposed new rule, carriers would submit the provider agreements with a completed checklist and certification, and the provider agreements would be deemed approved if not disapproved within 60 days after submission. In addition, the proposed new rule would clarify the types of alterations to the filed contracts that could be made without new submissions for approval being required. The proposed new rules would also impose an affirmative obligation upon carriers to affirmatively respond timely to Department requests for further information, if any, in order to avoid having the filing become inactive. The Department anticipates that the proposed amendments would allow for a more orderly and dynamic form filing process, and avoid undue delays in carrier operations.

The Department is proposing new rules at N.J.A.C. 8:38A-4.15C, 4.15.D, 4.15E, 4.15F and 4.15G setting forth standards for the provisions of provider agreements generally, and special standards that apply to provider agreements with certain types of health care providers or in certain situations. The proposed

new rule at N.J.A.C. 8:38A-4.15C sets forth standards for provider agreements that are similar to those existing currently at N.J.A.C. 8:38A-4.15, although the standards are structured somewhat differently. The proposed new rule would set forth the issues that all provider agreements must address, the issues that all provider agreements may address (within parameters), and the issues that no provider agreements may include. The proposed new rule at N.J.A.C. 8:38A-4.15D sets forth specific standards that would apply to provisions addressing termination and continuity of care requirements in provider agreements with health care professionals. The proposed new rule at N.J.A.C. 8:38A-4.15E sets forth standards that would apply to provisions addressing termination and continuity of care requirements in provider agreements with hospitals and certain other health care providers. The proposed new rules at N.J.A.C. 8:38A-4.15F sets forth additional standards that would apply to provider agreements with primary care providers and specialists. The proposed new rule at N.J.A.C. 8:38A-4.15G sets forth additional standards that would apply to provider agreements with hospitals. The proposed new rules substantially conform to the standards existing for provider agreements involving ODSs, in addition to being similar to existing standards at N.J.A.C. 8:38A-4.15. Also, some of the proposed new rules reinforce other provisions of existing rules or proposed amendments to rules (for instance, regarding termination and continuity of care, and round-the-clock coverage). The Department believes that the proposed new rules would enhance the standards for provider agreements and provide substantially more

guidance to carriers and other interested parties in developing provider agreements for use in New Jersey.

The Department is proposing a new rule at N.J.A.C. 8:38A-4.15H regarding transfer of risk from a carrier to other parties. The rules would limit to whom the carrier may transfer risk, essentially allowing a transfer of risk only to a secondary contractor who is an authorized payer (that is, a carrier, a dental plan organization, dental service organization or similar such entity regulated by DOBI), or a licensed ODS. The Department believes the proposed new rule would be helpful in providing guidance to carriers on the matter, and in understanding the inter-relationship among secondary contractors and ODSs.

The Department is proposing to amend N.J.A.C. 8:38A-4.16, regarding the requirement to report quality outcome measures, to make some grammatical corrections, and eliminate reference to the HeDaC, for consistency with other proposed amendments addressing that committee.

The Department is proposing a new rule at N.J.A.C. 8:38A-4.18 to address the issue of compliance by carriers with the HCQA in regards to health benefits plans that cover only limited services (such as vision plans, or specified alternative medicine providers only), or dental benefits plans. There are provisions of the HCQA and the rules contained within N.J.A.C. 8:38A for which it is impractical for carriers to comply when the product at issue is a limited service health benefits plan, or which, should the carrier comply, would not necessarily promote best practices and quality for the product. The Department recognizes this, and, operationally, has not required all such carriers offering limited services

health benefits plans or dental benefits plans to meet all of the regulatory requirements that apply to comprehensive health benefits plans. The Department is proposing the new rules on this subject matter in order to provide more complete and specific guidance for carriers in this matter.

At N.J.A.C. 8:38A-5.1, which sets forth the general requirements for the IHCAP, the Department is proposing several separate amendments. The Department is proposing an amendment to correct a citation, and an amendment to make a grammatical correction. The Department also is proposing several sets of language changes to state that: (1) all carriers should be complying with the standards set forth at N.J.A.C. 8:38-8.7 with respect to the IHCAP; (2) the per case cost for the IHCAP may be revised from time to time, and carriers are required to pay the cost that is in existence on the date that the IHCAP's assigned Independent Utilization Review Organization (IURO) completes its preliminary review of an appeal; and (3) the IUROs' decisions are binding upon carriers, consistent with the change in law that occurred pursuant to L. 2001, c. 1.

The Department is proposing to repeal N.J.A.C. 8:38A-5.2, because the rule is no longer relevant. N.J.A.C. 8:38A-5.2 set forth procedures that the Department would follow in reviewing carrier actions taken with respect to IURO recommendations. N.J.A.C. 8:38A-5.2 was promulgated to implement the provisions of section 12 of the HCQA as originally enacted (N.J.S.A. 26:2S-12). However, with the amendments to that section enacted pursuant to L. 2001, c. 1, which made the decisions of the IURO binding, i.e., requiring carrier compliance, the provisions of N.J.A.C. 8:38A-5.2 became moot. The Department now may

simply fine and otherwise penalize carriers that fail to comply with the decisions of the IURO.

The Department is proposing to repeal Exhibit 1 of the Appendix to N.J.A.C. 8:38A, which contains the (original version) of the IHCAP application form. For more detailed discussion of this proposed repeal, please refer to the summary of proposed changes to N.J.A.C. 8:38A-3.6(b), set forth above.

Because the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

Managed care, and the offering by non-HMO carriers of insurance policies with managed care features, such as UM programs and policy benefit designs that encourage the insured to use health care providers within specific networks, remains a significant segment of the insurance market in New Jersey. The estimates are that more than 1,000,000 New Jersey residents were covered in 2003 under insured network-based health benefits plans delivered in New Jersey by carriers other than HMOs, and carriers' combined earned premiums totaled approximately $1,288,000,000 for that year. Non-HMO carriers earned approximately $211,345,000 in premium on limited service network-based health benefits plans (such as dental only and vision only products) in New Jersey in 2003. (In contrast, HMOs covered approximately 2,100,000 individuals in 2003 – 1,371,000 members in the commercial market -- and earned approximately $5,669,000,000 in medical premium, with $3,794,000,000 being in the

commercial market.) The Department is not able to determine the number of people covered under insured policies that are not network-based, but nevertheless, include managed care features, such as UM, but it is likely, there are an additional number of New Jerseyans with such policies. While carriers are exploring new benefit designs to hold down medical costs and premium rates, it is unlikely that managed care or managed care health benefits plans will become obsolete in the near future.

The Department's purpose in proposing to readopt the rules at N.J.A.C. 8:38A with amendments and new rules is to assure the continued implementation and interpretation of the HCQA, which governs this dynamic market with the main purpose of promoting consumer protection by assuring that consumers have access to appropriate providers and coverage for medically necessary covered services. The Department believes that the proposed readoption with amendments and the proposed new rules will further the goals of the HCQA, as well as bring the tenets of the HCQA and its subsequent amendments in line with the tenets of the Health Maintenance Organization Act and its subsequent amendments (codified at N.J.S.A. 26:2J-2 et seq.), as well as the Organized Delivery Systems Act, and its subsequent amendments (codified at N.J.S.A. 17:48H-1 et seq.). The Department believes that the proposal will have a positive social impact.

The primary purpose of most of the proposed amendments and new rules is to add specificity or emphasize certain issues, in order to provide clearer guidance to carriers regarding their obligations and the rights that the

Department believes exist for consumers pursuant to the HCQA, so that carriers will understand their level of accountability in this market, and act accordingly. In addition, the proposed readoption with amendments and proposed new rules attempts to harmonize standards applicable in differing market segments, so that carriers have an increased opportunity to streamline certain operations and are able to focus their resources in more consumer-friendly endeavors. For instance, the Department believes that by amending the State's requirements regarding the two-stage internal UM appeals process to more closely fit with the general requirements for adverse determination appeals set forth by the Federal government with respect to group health plans, carriers would be in a position to minimize the number of variations they must maintain in their appeals policies and procedures, and that information provided to consumers by carrier personnel or contractors would be more accurate and appropriate for all covered persons and any representative who may appeal on a covered person's behalf. This is beneficial to all interested parties. The Department is also proposing amendments to the proposed readoption that the Department believes would help to assure that all consumers to whom a carrier intends to offer its managed care product will be adequately served, while retaining a certain degree of flexibility for both carriers and health care providers to establish programs suitable to changing business environments and technology. For instance, the Department is proposing amendments to the proposed readoption intended to promote access by covered persons to after-hour services, and encourages carriers and health care providers to direct covered persons to appropriate care

settings (which may not necessarily be a hospital emergency department), but allows carriers and their health care providers to utilize multiple designs to achieve this goal. The Department believes that these proposed amendments to the proposed readoption would be a benefit to all interested parties.

Economic Impact

The Department does not consider the proposed readoption with amendments or the proposed new rules to be imposing any new compliance costs upon carriers or other parties that may be affected indirectly by the rules, since the newly stated requirements do not exceed what the Department has expected in practice. One possible exception to this could be the proposed amendment requiring carriers to send certain notices to participating providers via certified mail and to all addresses of record. However, whether this actually represents an adverse economic impact for any particular carrier depends upon the carrier's current method of operation. As with most proposals regarding this particular market, whether there is an adverse or positive economic impact upon the carriers and their contractors depends upon how the carrier currently operates, whether the carrier may need to revise its operations in order to comply with the proposal, and the methods that the carrier may elect to employ in order to come into compliance when necessary. The Department is rarely in a position to posit the degree of economic impact upon the regulated industry, or the purchasers of the industry's products. However, based on the proposed readoption with amendments and proposed new rules, the Department

anticipates that some carriers will incur costs to revise certain of their disclosure notices, and processes for distribution of such notices. The Department further anticipates that some carriers could incur costs refining their networks, although most carriers tend to exceed the minimum standards for network adequacy generally. The Department anticipates that some carriers will derive a positive economic impact from the proposed readoption with amendments and new rules to the extent that a carrier is able to refine its operations regarding appeals, and is able to function more efficiently with respect to design and filing of provider agreements.

The Department does not believe there will be any specific economic impact upon health care providers or covered persons as a result of the proposed readoption with amendments or proposed new rules. Although the Department believes that the proposed readoption with amendments and proposed new rules could result in some changes in carrier operations, policies and procedures, and make carriers more accountable in certain areas, the Department believes that any increases or decreases in costs related to such changes will be modest at most, and will not be significant enough to translate into an economic impact upon covered persons or health care providers.

Federal Standards Statement

Currently, covered persons have a right to appeal certain determinations pursuant to both Federal and State law. The United States Department of Labor (USDOL) proposed rules at 29 C.F.R. 2560.503-1, pursuant to sections 503 and

505 of ERISA, 29 U.S.C. 1133 and 1135, requiring that employee benefit plans have in place reasonable claims procedures. The regulation became effective July 1, 2002 (and all coverage subject to the regulations was to be in compliance no later than January 2003). In accordance with the Federal regulation, a principle tenet for demonstrating a reasonable claim procedure is the ability of the claimant to appeal an adverse claim determination. Because of the manner in which the Federal regulations define "claim" and "group health plan," the Federal regulations and New Jersey's rules requiring carriers subject to the HCQA (including HMOs) to establish an internal UM appeal system, overlap in terms of their applicability, although there are areas in which each law applies distinctly. For instance, the Federal regulations do not apply to any coverage not otherwise subject to ERISA, while New Jersey rules do, and conversely, the State rules apply only to those products defined as health benefits plans, while the Federal regulations apply to other types of health coverage (for instance, disability policies).

The Federal regulations do not preempt State rules, except when compliance with the State rules would make it impossible for the regulated entity to comply with the Federal regulations as well. (See, 29 C.F.R. 2560.503-1(k)). In June of 2002, the Department issued Bulletin 2002-01 notifying carriers that the Department would not be enforcing one provision of the rules regarding the Stage 1 internal appeal process (N.J.A.C. 8:38-8.5 and N.J.A.C. 8:38A-3.5), which required that the same physician who issued the initial UM denial review the appeal at Stage 1. This was inconsistent with the Federal regulations which

prohibit the initial decision-maker from rendering any decision on the appeal. The Department suspended the requirement across all health benefits plans, but all other requirements remained in effect, and for the most part, carriers appear to have found ways to comply with both the State rules and the Federal regulations.

Through this proposed readoption with amendments, the Department is attempting to simplify the compliance process for carriers by bringing the State rules into closer alignment with the Federal regulation. Arguably, the State rules are more stringent than the Federal regulations; however, the proposed readoption with amendments would, for the most part, make the State rules less stringent than they currently are, and in all instances, merely establish standards that are explicitly permitted by the Federal regulations, but not explicitly required. For instance, the Federal regulations address the length of time during which an appeal is to be completed, prohibits more than a two-stage appeal process, but notes that, if a two-stage process is used, then both stages of the appeal must be completed within the total allotted time set forth by the Federal regulations. New Jersey's rules require a two-stage internal appeal process, and proposed amendments require that both stages are completed within the allotted timeframe. The proposed rules would maintain a relatively brief timeframe for completion of Stage 1 appeals, and a longer timeframe for completion of Stage 2 appeals, similar to the current rules. (It may be noted that the Federal regulations have no bearing on the IHCAP.)

The Department has elected to propose retention of some more stringent standards in order to strike a balance between those carriers that have to struggle to make their systems compliant with both the State and Federal laws, and those carriers that would not need to change their systems at all because of the Federal regulations. Further, because the more stringent standards are the ones that have been in place in New Jersey since at least May of 2000 (since 1997 with respect to HMOs), the Department does not consider the more stringent features being retained as representing any particular hardship for carriers doing business in the State. The Department does not believe that any carriers would have to incur any additional staffing, systems changes or costs in order to comply with the more stringent timeframes of the existing New Jersey rules proposed for readoption with amendments. Further, the Department believes that the shorter timeframe is more beneficial to members who have postponed obtaining health care services they believe are medically necessary pending the outcome of an appeal.

I certify that the foregoing analysis permits the public to understand accurately and plainly the purposes and expected consequences of the proposed amendments and proposed new rules.

_____

Fred M. Jacobs, M.D., J.D., Commissioner

Department of Health and Senior Services

Jobs Impact

The Department does not anticipate that the proposed readoption with amendments, or the proposed new rules will result in the creation or loss of any jobs.

Agriculture Industry Impact

The Department does not expect the proposed readoption with amendments, or the proposed new rules to have any impact upon the agricultural industry.

Regulatory Flexibility Analysis

The proposed readoption with amendments and proposed new rules essentially maintain all of the current reporting, recordkeeping and compliance requirements of existing N.J.A.C. 8:38A, although in some instances, the proposed amendments may clarify certain of the recordkeeping requirements, and expand some of the compliance requirements. In addition, although the Department does not believe it is so, some carriers may be "small businesses" as that term is defined at N.J.S.A. 52:14B-16, in that they are resident in New Jersey, employ fewer than 100 people, and are not dominant in their industry. Accordingly, the Department is providing a regulatory flexibility analysis.

Numerous reporting, recordkeeping and compliance requirements are set forth within the rules at N.J.A.C. 8:38A, including the following: complaints data,

appeals data, internal performance indicators, continuous quality improvement plans and revisions, external quality review organization reports, consumer and member disclosures, submission for review of forms of contracts for issue to contract holders, and forms of contracts with intermediaries and health care providers. The Department is proposing to amend many of the recordkeeping requirements as part of the proposed readoption.

The Department does not offer regulatory flexibility to carriers with respect to reporting or recordkeeping requirements, even when the carrier meets the definition of a "small business," because the Department does not believe that the resultant reduction in consumer protection is warranted or desirable, or consistent with the Legislative intent behind enactment of the HCQA.

Smart Growth Impact

The Department does not expect the proposed readoption with amendments, the proposed new rules or the proposed repeal to have any impact upon the achievement of smart growth or the implementation of the State Development and Redevelopment Plan.

Full text of the proposed readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:38A.

Full text of the proposed amendments, proposed new rules and proposed repeal follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

CHAPTER 38A. HEALTH CARE QUALITY ACT [APPLICATION TO]: GENERAL IMPLEMENTATION FOR INSURANCE COMPANIES, HEALTH SERVICE CORPORATIONS, HOSPITAL SERVICE CORPORATIONS, AND MEDICAL SERVICE CORPORATIONS

8:38A-1.2 Definitions

For the purposes of this chapter, the words and terms set forth below shall have the following meanings, unless the word or term is further defined within a subchapter of this chapter, or the context clearly indicates otherwise.

…

"Adverse determination" means a denial, reduction, termination or other limitation of covered health care services, or benefits therefor, resulting from the application of a utilization management review in which the carrier determines that a covered service is not medically necessary or appropriate, is cosmetic instead of medically necessary, is dental instead of medical, or is experimental or investigational in the particular circumstance. The term includes situations in which the covered person seeks to have services covered when performed by a specific provider or type of provider (usually non-participating) because the covered person believes it is medically necessary to do so, but the carrier disagrees; however, the term does not include situations in which the covered person seeks to have payment for the performance of services by a specific

provider based solely upon the covered person's or a referring provider's preference unrelated to medical necessity.

…

"Continuity of care period" means the time period beginning immediately following the date of termination of a contract between a carrier and a provider (existing directly or through a secondary contractor) during which the terms of the contract are extended so that the carrier's covered persons may continue to utilize the services of the terminated provider. Also may be referred to as the "four-month extension period."

…

"Credentialing" means the process of collecting and validating the professional qualifications of a health care professional and evaluating those qualifications against a carrier's standards of qualifications for participation in the carrier's provider network.

…

"Health benefits plan" means a policy or contract for the provision of hospital or medical services or the payment of benefits [for hospital and medical expenses or the provision of hospital and medical services] therefor that is delivered or issued for delivery in this state by a carrier. The term "health benefits plan" specifically includes:

1. Medicare supplement coverage and risk contracts for the provision of health care services covered by Medicare to the extent that state

regulation of such contracts or policies is not otherwise preempted by Federal law; and

2. Any other policy or contract not otherwise specifically excluded by statute or this definition.

The term "health benefits plan" specifically excludes:

1. Accident only policies;

2. Credit health policies;

3. Disability income policies;

4. Long-term care policies;

5. CHAMPUS supplement coverage;

6. Hospital confinement indemnity coverage;

7. Coverage arising out of a workers' compensation law or similar such law;

8. Automobile medical payment insurance or personal injury protection insurance issued pursuant to N.J.S.A. 39:6A-1 et seq.; and

9. Coverage for medical expenses contained in a liability insurance policy.

“Health care facility” means a facility licensed pursuant to N.J.S.A. 26:2H-1 et seq., as that law is amended from time to time.

“Health care professional” means an individual who, acting within the scope of his or her licensure or certification, provides health care services, and includes, but is not limited to, a physician, dentist, nurse, pharmacist or other

health care professional whose professional practice is regulated pursuant to Title 45 of the New Jersey statutes.

"IHC Program" means the Individual Health Coverage Program set forth at N.J.S.A. 17B:27A-2 et seq., and any rules promulgated pursuant thereto.

"Independent Health Care Appeals Program" or “IHCAP” means the external appeals process [for] through which a covered person or provider on behalf of the covered person with the covered person's consent, [to] may appeal [a decision] an adverse utilization management determination of a carrier to deny, reduce or terminate services or payment of benefits [resulting from a decision by a carrier with respect to the covered person which services are otherwise covered under the health benefits plan] for services that are otherwise covered under the terms of the health benefits plan in which the covered person is insured or enrolled, including decisions to deny covered services, or payment therefor, on the basis that the request is for cosmetic services only, that the service is not of a medical nature (or, with respect to dental health benefits plans, that the service is not dental in nature), or that the service is experimental or investigational in the instance at hand.

"Independent utilization review organization" or "IURO" means an independent organization with which the Department contracts to provide independent reviews through the Independent Health Care Appeals Program of carrier determinations regarding medical necessity or appropriateness of services which are contested by the covered person or a provider on behalf of the covered person, and that is comprised of health care professionals, and has

the capability, as necessary, to contract with additional health care professionals representative of the classes of active health care professionals in New Jersey, but which, as an organization, is not otherwise licensed as a health care provider in New Jersey or elsewhere and has no owners or shareholders that are health care facilities or carriers that, individually or in combination, have more than a 5 percent interest in the organization.

...

"Management agreement" means a contract between a carrier and an organized delivery system required to be licensed or certified in accordance with N.J.S.A. 17:48H-1 et seq., and rules promulgated pursuant thereto at N.J.A.C. 11:22-2 and N.J.A.C. 8:38B.

"Medical necessity" or "medically necessary" means that a treatment or service is appropriate and consistent with a patient's diagnosis and that, in accordance with accepted standards of practice, the treatment or service cannot be omitted without adversely affecting the patient's condition or the quality of care.

"Organized Delivery System" or "ODS" means that an entity that contracts with a carrier to provide or arrange for the provision of one or more types of health care services to a carrier's covered persons and that is required to be certified in accordance with N.J.A.C. 8:38B or licensed in accordance with N.J.A.C. 11:22-4.

…

"Provider" means any [physician or other] health care professional[, hospital, facility or other person who is licensed or otherwise authorized to provide health care services or other services in the state or jurisdiction in which the services are furnished] or health care facility.

"Secondary contractor" means a person who agrees to arrange for the provision of one or more services or supplies for a carrier's covered persons. [A primary contractor also may be a secondary contractor when acting as a broker or administrator for the rendering of services or supplies that, in scope of licensure, type or quantity, the primary contractor (provider) alone could not offer directly to the carrier's covered persons.] A secondary contractor may be a carrier, an HMO, a dental service corporation, a dental plan organization, a fraternal benefit society, or an ODS.

…

"Service agreement" means a contract between a carrier and another entity for the performance of a function or functions of the carrier by the entity, directly or through one or more subcontractors, on the carrier's behalf. For purposes of this chapter, service agreements are those agreements addressing one or more of the following functions: complaints handling, appeals handling, member services, marketing, claims processing, network management, credentialing, medical management, quality improvement, utilization management, case management, disease management, and the arrangement for the provision of health care services by a secondary contractor, but not including an organized delivery system required to be licensed or certified in

accordance with N.J.S.A. 17:48H-1 et seq., and rules promulgated pursuant thereto at N.J.A.C. 11:22-2 and N.J.A.C. 8:38B.

. . .

8:38A-1.3 Compliance time frames

(a) through (d) (No change.)

(e) With respect to form filings of provider agreements and management agreements inforce on (the date of readoption of this chapter), such agreements not in compliance with this chapter within (one year following the effective date of the readoption of this chapter) shall be deemed withdrawn January 1, 2006.

8:38A-2.2 HCQA Registration Form

(a) Carriers shall complete and submit to the Department and the Department of Banking and Insurance the HCQA Registration Form, available from the Department upon request, describing, if required, the carrier's internal appeal process, by which covered persons, or a provider on behalf of a covered person (with the covered person's consent), may appeal a carrier's UM decision, and the carrier's notice to covered persons of the right to appeal a carrier's final UM decision to the Independent Health Care Appeals Program.

1. through 2. (No change.)

3. Carriers shall file a copy of the HCQA Registration Form with the Department [and the Department of Banking and Insurance] at the following address:

New Jersey State Department of Health and Senior Services

Office of Managed Care

PO Box 360

Trenton, NJ 08625-0360

[and

New Jersey Department of Banking and Insurance

Managed Care Bureau

Division of Life and Health Division

P.O. Box 325

Trenton, NJ 08625-0325]

(b) through (c) (No change.)

8:38A-2.3 Disclosure requirements

(a) Carriers shall provide to each subscriber within no more than 30 days following the effective date of coverage, and upon request thereafter, through a handbook, certificate or other evidence of coverage designed for covered persons, information describing the following:

1. through 3. (No change.)

4. Use of the "911" emergency response system whenever a covered person has a potentially life-threatening condition, and a statement that "911" information is included on the covered person's insurance identification card.

i. (No change.)

ii. In complying with (a)4i above, carriers may elect to phase-in the 911 information on insurance identification cards, so long as all covered persons of a carrier has an insurance identification card that meets the requirements of (a)4i above no later than 24 months following [(the operative date of this chapter)] May 1, 2000;

5. through 7. (No change.)

(b) through (c) (No change.)

8:38A-2.5 Other rights of covered persons

(a) (No change.)

(b) Carriers' policies and procedures shall address at least the following:

1. (No change.)

2. The right of covered [person] persons to have access to services, and payment of appropriate benefits therefor, when medically necessary, including availability of care 24 hours a day, seven days a week for urgent or emergency conditions, if covered;

3. through 4. (No change.)

8:38A-2.6 Emergency and urgent care services

(a) If a carrier's policy or contract provides benefits for emergency or urgent care services, the carrier shall include benefits for the coverage of trauma services at any designated Level I or II trauma center as medically necessary, which shall be continued at least until, in the judgment of the attending physician,

the covered person is medically stable, no longer requires critical care, and can be transferred safely to another facility.

1. If a carrier requests transfer of a covered person to another hospital, whether or not participating in the carrier's network, the transfer shall be effected in accordance with Federal regulations at 42 C.F.R. 489.20 and 489.24, as well as N.J.A.C. 8:43G-12.7 when one or both hospitals is a New Jersey general hospital.

2. In the event that a covered person is covered under a managed care plan, and the carrier fails to request a transfer of the covered person to a participating hospital upon notice of the covered person's presence at a nonparticipating hospital or notice that the covered person is medically stable, whichever occurs later, the carrier shall consider the covered person as if he or she were accessing service in-network, and the covered person's cost sharing, if any, shall be the at the network cost sharing level for covered services.

(b) In addition to (a) above, the contract or policy shall pay for coverage of a medical screening examination provided upon a covered person's arrival in a [hospital] hospital's emergency department, as required to be performed by the hospital in accordance with Federal law and as specified at N.J.A.C. 8:43G-12, including the costs of diagnostic tests, if any, but only as necessary to determine whether a covered person has an emergency medical condition [exists].

1. Requirements applicable to the medical screening shall be as set forth by the provisions of N.J.A.C. 8:43G-12.7 related to the medical screening requirement.

2. For purposes of this section, an emergency medical condition shall be as defined at N.J.A.C. 8:43G-12.6.

3. Nothing herein shall be construed to prevent a carrier and a hospital from negotiating a predetermined rate of reimbursement for medical screenings, and mutually agreeing as to what services and costs are included within the negotiated predetermined rate, and which costs, if any will be paid in addition to any predetermined rate.

4. Nothing herein shall be construed to prevent a carrier from applying a cost-sharing requirement to the provision of emergency services.

8:38A-3.2 Disclosure requirements

(a) (No change.)

(b) The statement that a covered person has a right to appeal a carrier's utilization management decision at the option of the covered person through the Independent Health Care Appeals Program, including:

1. through 3. (No change.)

4. A statement that the decision of the Independent Health Care Appeals Program is [not] binding upon [either] the carrier [or the covered person].

8:38A-3.3 Designation of a medical director

(a) The carrier shall designate a physician licensed to practice medicine in New Jersey to serve as the medical director for the carrier with respect to its

contracts or policies delivered in this State to which a utilization management program applies.

1. In the case of a dental benefits plan, the medical director may be a dentist, and the term medical director may substituted with the term dental director, but the responsibilities of the dental director shall be as set forth for the position of medical director in these rules.

2. In the case of other limited benefits plans in which the policy or contract does not provide any benefits for expenses or coverage of services rendered by a health care professional that is a physician or surgeon licensed pursuant to N.J.S.A. 45:9-1 et seq., carriers shall not be required to designate a physician licensed to practice medicine in New Jersey as the medical director, but alternatively may designate a health care professional licensed in New Jersey to perform the services that are covered under the limited health benefits plan.

(b) (No change.)

8:38A-3.4 Utilization management program

(a) A carrier's UM program shall be under the direction of the medical director, or his or her designee (who shall be a physician licensed to practice medicine in the State of New Jersey, except as N.J.A.C. 8:38A-3.2(a)1 and 2 apply), and shall be based on a written plan, reviewed annually by the carrier, and available for review by the Department upon request, specifying at least:

1. (No change.)

2. The policies and procedures to evaluate clinical necessity, access, appropriateness, and efficiency of services;

3. through 5.

6. [The] With respect to a carrier's health benefits plan, the development of measures for evaluating the carrier's UM program, including outcome and process measures when the carrier utilizes a gatekeeper system or practice guidelines for its managed care product(s);

7. [A] With respect to a carrier's health benefits plan, a system for covered persons, and providers on behalf of covered persons (with the covered person's consent) to appeal UM determinations in accordance with the procedures set forth at N.J.A.C. 8:38A-3.5; and

8. [A] With respect to a carrier's health benefits plan, a mechanism to evaluate the satisfaction of covered persons with the appeals system, which mechanism shall coordinate with the carrier's CQI program required pursuant to N.J.A.C. 8:38A-3.8.

(b) Carriers shall ensure that UM determinations are based on written clinical criteria and protocols developed with involvement from practicing physicians and other licensed health care providers and based upon generally accepted medical standards.

1. (No change.)

2. The carrier shall make the criteria readily available, upon request, to covered persons and [interested] participating providers [except that internal or proprietary quantitative thresholds for UM is not required to be

released to covered persons or providers pursuant to this subchapter], if any, or providers treating a carrier's covered person.

i. (No change.)

(c) The carrier shall provide access to UM services as follows:

1. (No change.)

2. [If the carrier requires preauthorization for use of emergency departments or for reimbursement of services rendered under an emergency or urgent situation,] For all other utilization-related inquiries, the carrier shall have [a] an adequate number of registered professional [nurse or physician] nurses and physicians so that staff shall be immediately available by phone via a dedicated phone number seven days a week, 24 hours a day to render UM determinations to providers.

i. The carrier may make contact by secured facsimile and/or electronic mail between its utilization management staff and providers an option.

iii. The carrier shall at all times have an adequate number of dedicated telephone lines available to assure that responses to phone calls and all other transmissions are timely and consistent with the medical exigencies of the case.

(d) The carrier shall have written policies and procedures, available for review by the Department upon request, that address the responsibilities and qualifications of staff who render determinations to authorize admissions, services, procedures or extensions of stay meeting the following:

1. All determinations to deny or limit an admission, service, procedure or extension of stay, or benefits therefor, shall be made in accordance with the clinical and medical necessity criteria developed in accordance with (b) above, [and]

2. All determinations to deny or limit an admission, service, procedure or extension of stay, or benefits therefor, shall be rendered by a physician under the clinical direction of the medical director required pursuant to N.J.A.C. 8:38A-3.3, except that a dentist rather than a physician may render an adverse determination with respect to dental services, and other health care providers may render an adverse determination only with respect to limited health benefits plans subject to N.J.A.C. 8:38A-3.2(a)2.

i. The physician, dentist or other health care professional shall communicate the determination directly to the provider or, if this is not possible, the physician shall supply his or her name, telephone number and where he or she may be reached so that the provider may contact the physician for further discussion.

ii. The physician, dentist or other health care professional rendering the determination shall be available immediately to discuss the determination with the treating provider in urgent or emergency cases and on a timely basis for all other cases as required by the medical exigencies of the situation.

[2.] 3. All determinations shall be made and communicated on a timely basis, as required by the exigencies of the situation, consistent with the

timeframes of 29 C.F.R. 2560.503-1(f) set forth for group health plans with respect to urgent care claims, concurrent care decisions and other claims that are pre-service or post-service claims, as those terms are defined or described in the Federal rules.

i. Nothing herein shall be construed to prevent the carrier and its providers from establishing administrative procedures regarding the process for obtaining utilization management determinations, so long as such administrative procedures are not inconsistent with these rules.

(e) (No change.)

(f) A carrier shall provide written notice [within five days] in accordance with (d)3 above, or sooner if the medical exigencies dictate, [upon request,] of any utilization management determination [to deny coverage or authorization of services or payment of benefits therefor otherwise covered under the contract or policy of the covered person], and shall include an explanation of the appeal process in all written notices regarding adverse determinations.

1. A carrier's explanation of the appeal process shall be consistent with the process required at N.J.A.C. 8:38A-3.5 and 3.6.

2. All forms of communication with the covered person or provider, including verbal communications, shall include information regarding the covered person's and provider's right to appeal an adverse determination, including the right to initiate the determination by telephone.

3. The notices shall specify the timeframe following receipt of the written adverse determination during which an appeal of the adverse determination may be initiated.

4. In addition, the carrier shall comply with the requirements of 29 C.F.R. 2560.503-1(g), including setting forth the specific clinical criteria on which the adverse determination is based, except that the carrier need not include reference to the right to bring civil actions when the covered person is not covered under a group health plan.

8:38A-3.5 Internal utilization management appeals process

(a) A carrier shall establish an appeal process whereby a covered person or a provider acting on behalf of the covered person, with the covered person's specific consent, may appeal any UM decision [resulting in a denial, termination or limitation of services or the payment of benefits therefore covered under the contract or policy] that is an adverse determination.

(b) (No change.)

(c) Carriers shall provide a written description of the appeal process and the carrier's decision on an appeal to providers upon request, and upon the conclusion of each stage of the appeal process, when the provider is making the appeal on behalf of a covered person with the covered person's consent.

1. The carrier’s written explanation shall include a statement that specific consent of a covered person is required for providers to institute an appeal on behalf of a covered person in order for the appeal to be processed

pursuant to the carrier's internal appeal mechanism (except as 29 C.F.R. 2560.503-1(b)(4) applies), and N.J.A.C. 8:38A-3.6.

(d) The carrier shall not establish nor maintain any policies or procedures that prohibit or discourage a covered person from discussing or exercising the right to an appeal, including the right to designate a provider to act on behalf of the covered person in the appeal process.

1. Every carrier shall permit providers to represent covered persons in appeals, but every carrier shall require that the provider have evidence of specific consent given by the covered person following an adverse determination in order to act on the covered person's behalf, except as 29 C.F.R. 2560.503-1(b)(4) may require otherwise with respect to urgent care as defined in Federal regulation at 29 C.F.R. 2560.503-1(m)(1).

i. No carrier shall postpone processing of an appeal request initiated by a provider pending receipt of written evidence of the covered person's consent, but the carrier may withhold dissemination of the determination on the appeal pending such evidence.

ii. In the even that the carrier requires the consent of the covered person to be evidenced via completion of a carrier-generated form, the carrier shall:

(1) Include such form with each initial written adverse determination;

(2) Permit any type of health care provider to act on the covered person's behalf with consent;

(3) Not require that witnesses, if any, to the consent have a specific relationship to the covered person or the health care provider, have a specific rank or title, or be a notary;

(4) Not require that the consent be submitted in a timeframe that is less than the timeframe during which covered persons could submit an appeal themselves; and

(5) Not require different or additional consents to be provided for different stages of the appeal process.

iii. A carrier shall not limit a covered person's opportunity to have representation by a willing health care provider on an appeal of an adverse determination by requiring that the health care provider waive his or her ability to act on a covered person's behalf with the covered person's consent as a condition of securing certain contractual rights by the health care provider under the terms of the provider agreement.

(e) Carriers shall establish an appeal process in two stages, with the stage 1 appeal being an informal process, and stage 2 being a formal process.

1. The carrier shall permit a covered person or a provider acting on the covered person's behalf to file an appeal for at least an 180-day period following receipt of the initial written adverse determination.

i. Regardless of whether a carrier establishes the minimum 180-day time limit for the filing of appeals set forth in (a) above or provides a greater time limit for the filing of appeals, the time limit established by

the carrier for filing of appeals shall not begin to run until at least 5 business days following the date that the carrier issued the adverse determination.

ii. Nothing herein shall be construed to limit the ability of the carrier or provider acting on behalf of the covered person to initiate an appeal telephonically immediately upon verbal notice of an adverse determination.

2. The carrier shall permit a covered person or a provider acting on the covered person's behalf to file an appeal for at least an 180-day period following the receipt of the written stage 1 determination.

i. Regardless of whether a carrier establishes the minimum 180-day time limit for the filing of appeals set forth in (a) above or provides a greater time limit for the filing of appeals, the time limit established by the carrier for filing of appeals shall not begin to run until at least 5 business days following the date that the carrier issued the adverse determination.

(f) [Carriers shall provide in stage 1 for a covered person (or his or her designated provider if the covered person has consented to having a provider act in his or her behalf) to have an opportunity to speak, regarding an adverse service or benefits determination, with the carrier's medical director, or the medical director's designee who rendered the adverse determination.

1. Stage 1 appeals shall be concluded as soon as possible in accordance with the medical exigencies of the case, but in no event shall exceed:

i. 72 hours in the case of an appeal from a determination regarding urgent or emergency care (which shall include all situations in which the covered person is confined in an inpatient facility); and

ii. Five business days in the case of all other appeals.

2. At the conclusion of stage 1, the carrier shall include a written explanation of the covered person's right to make a stage 2 appeal, including the applicable time limits, if any, for making the appeal, and to whom the appeal should be addressed.] The carrier shall have a Stage 1 appeal reviewed by a physician who has not previously reviewed the service request, and who is not subordinate to the physician that rendered the initial adverse determination, and shall contact covered persons and providers regarding the determination on the appeal as expeditiously as possible, contingent with the medical exigencies of the case.

1. The reviewer shall have appropriate training and experience in the field of medicine that would normally handle the case under appeal.

2. The reviewer shall have an affirmative obligation to try to obtain more information from the appellant prior to rendering an adverse determination on the case, if the reviewer believes he or she needs additional information.

3. Determinations on appeals regarding urgent care requests, including requests for inpatient services made while a covered person is an inpatient and/or regarding continued lengths of stay, shall be rendered in no more than 72 hours following receipt of the appeal request.

4. Determinations regarding appeals of all other types of requests shall be rendered contingent with the exigencies of the situation, but in no instance greater than:

i. Five business days following the date of receipt of an appeal in the case of a UM pre-service claim, as pre-service claim is defined at 29 C.F.R. 2560.503-1(m); or

ii. Thirty days following the date of receipt of an appeal in the case of a UM post-service claim, as post-service claim is defined at 29 C.F.R. 2560.503-1(m).

5. While a carrier shall disseminate the determination rendered for an appeal as expeditiously as possible, the carrier shall issue a written notice of the determination to the covered person and the provider acting on behalf of the covered person.

i. A carrier shall include in a written notice of adverse determination an explanation of the covered person's right, or that of the provider acting on behalf of the covered person to continue to pursue an appeal, setting forth the process, including the right to initiate the appeal by telephone, and the timeframe following receipt of the written adverse determination during which an appeal of the adverse determination may be initiated.

ii. In addition, the carrier shall comply with the requirements of 29 C.F.R. 2560.503-1(g), except that the carrier need not include reference to the right to bring civil actions if the covered person is not covered under a group health plan.

(g) Carriers shall provide in stage 2 appeals for a covered person (or the covered person's designated provider, if the covered person [has] specifically consented to have a provider act in his or her behalf following receipt of the initial adverse determination) to pursue his or her appeal before a panel of physicians and/or other providers selected by the carrier who have not been involved in the UM decision at issue.

1. [The panel shall have] Panel members shall not have been involved in the adverse determination at issue.

2. The panel shall have one or more members with appropriate training and experience in the field of medicine that would normally handle the case under appeal, or have access to and utilize the knowledge of consultant providers who are trained or who practice in the same specialty as would typically manage the case at issue, or such other licensed provider as may be mutually agreed upon by the parties.

i. The consulting provider(s) shall not have been involved in the UM decision at issue.

ii. The carrier shall allow the consulting provider(s) to participate with the panel in the review of the case if so requested by the covered person (or the covered person's designated provider if the covered person has consented to having a provider act in his or her behalf) when the carrier does not have panel members available with appropriate training and experience in the field of medicine that would normally handle the case under appeal, or if:

(1) The covered person or provider acting on the covered person's behalf disputes that the carrier's panel members have appropriate training and experience in the filed of medicine that would normally handle the case under appeal; or

(2) There are multiple categories of licensed health care professionals that may handle the case under appeal, the carrier's panel composition and consultants do not include all such licensed health care professionals, and the covered person or provider acting on the covered person's behalf request participation by another category of licensed health care professional, but only if the services at issue in the appeal are within the proposed licensed health care professional's scope of practice.

[2.] 3. The carrier shall send to the covered person (or designated provider if the covered person has consented to having a provider act in his or her behalf) an acknowledgment of the filing of a stage 2 appeal in writing within no more than 10 business days of receipt by the carrier of the appeal.

i. The carrier shall include in the notice the right of the covered person or provider acting on the covered person's behalf to request participation by other health care professionals in the panel's deliberation, if such information has not been provided already.

[3.] 4. The carrier shall conclude the stage 2 appeal as soon as possible after receipt of the appeal by the carrier in accordance with the medical exigencies of the case, but in no event shall exceed:

i. [72] Seventy-two hours in the case of appeals of determinations regarding urgent or emergent care (which shall include all situations in which the covered person is confined in an inpatient facility); [and]

ii. [20 business days in the case of all other appeals] Fifteen days in the case of UM pre-service claims, as pre-service claim is defined at 29 C.F.R. 1560.503-1(m); or

iii. Thirty days in the case of UM post-service claims, as post-service claim is defined at 29 C.F.R. 2560.503-1(m).

[4. Notwithstanding (g)3ii above, a carrier may extend the review period for up to an additional 20 business days where the carrier can demonstrate reasonable cause for the delay beyond its control, but only if the carrier provides a written progress report and explanation for the delay to the satisfaction of the Department and written notice to the covered person and provider, as appropriate, within the original 20 business day review period.]

5. In the event the stage 2 appeal results in a denial, the carrier shall provide the covered person and/or provider, as appropriate, with written notification of the denial and the reasons therefor together with a written notification, which shall be in addition to complying with the requirements of 29 C.F.R. 2560.503-1(j), of his or her right to proceed to an appeal through the Independent Health Care Appeals Program, including:

i. through ii. (No change.)

6. Notwithstanding (g)4 above, a carrier shall not be required to provide information regarding the right to bring a civil action under Federal law or

include the statement set forth at 29 C.F.R. 2560.503-1(j)(5)(iii) in determination notices issued to covered persons covered under a health benefits plan other than a group health plan.

7. A carrier shall not provide a stage 2 appeal to any covered person (or the covered person's designated provider if the covered person has consented to having a provider act in his or her behalf) until a covered person's right to a stage 1 appeal is exhausted.

8:38A-3.6 Independent health care appeals process

(a) Any covered person, and any provider acting on behalf of a covered person with the covered person's specific consent, who is dissatisfied with the final results of a carrier's internal appeals process shall have the right to pursue his or her appeal through the Independent Health Care Appeals Program to an independent IURO.

1. A covered person and any provider acting on behalf of a covered person with the covered person's consent shall exhaust all appeal rights he or she may have under the policy or contract with the carrier prior to making application to pursue an appeal through the Independent Health Care Appeals Program, except that the covered person and any provider acting on behalf of a covered person with the covered person's consent shall be relieved of the carrier's internal appeal process and may pursue an appeal through the Independent Health Care Appeals Program if the carrier fails to comply with the

requisite timeframe for rendering a determination on an appeal set forth at N.J.A.C. 8:38A-3.5[:

i. A determination on any appeal regarding urgent or emergency care is not forthcoming from the carrier within 72 hours of receipt by the carrier of notice (in the manner required under the policy or contract) of the appeal;

ii. A determination on an initial appeal, other than one regarding urgent or emergency care, is not forthcoming from the carrier within five business days of the date that the carrier received notice (in the manner required under the policy or contract) of the appeal; or

iii. A determination of a subsequent level of appeal, other than one regarding urgent or emergency care, is not forthcoming from the carrier within 20 business days of the date that the carrier received notice (in the manner required under the policy or contract) of the appeal, except as N.J.A.C. 8:38A-3.5(g)4 applies].

2. A covered person and any provider acting on behalf of a covered person with the covered person's consent dissatisfied with the carrier's appeal process for reasons set forth in (a)1[i, ii, or iii] above shall certify on the appeal form that one or more determinations from the carrier have exceeded the time frames [set forth in (a)1i, ii or iii above], and that the covered person or the covered person's provider have in no way hindered the carrier in making the determination by failing to provide the carrier with all requested information relevant to the determination.

3. (No change.)

(b) To initiate an appeal through the Independent Health Care Appeals Program, a covered person or provider acting on behalf of a covered person with the covered person's consent shall, within 60 days [from] after the date of receipt of the carrier's final determination, or the last date of filing of an appeal by the covered person or provider in the situation in which the covered person or provider acting on behalf of a covered person with the covered person's consent believes the carrier has failed to meet required time frames, file an application with the Department[, as set forth in Exhibit 1 of the chapter Appendix, incorporated herein by reference].

1. through 2. (No change.)

3. The carrier shall include an application form with every notice of adverse determination for Stage 2 appeals, or upon request following initiation of an appeal by a covered person or by a health care provider acting on the covered person's behalf with the covered person's specific consent.

4. Carriers may obtain the application form from the Department at the address set forth in (b)2 above upon request, either in electronic or paper format, but it is the carrier's responsibility to maintain adequate supplies of the application form.

(c) The covered person or provider acting on behalf of a covered person with the covered person's consent shall submit a fee of $25.00 per application, unless there is submitted with the application a demonstration of the covered person's financial hardship, in which event, the covered person may submit no

fee until a decision is made by the Department as to whether the covered person qualifies for a reduced fee based on financial hardship.

1. The Department will determine a covered person eligible for a reduced fee on the basis of financial hardship if the covered person submits evidence that one or more [covered] person [of] in the household is receiving assistance from the Pharmaceutical Assistance to the Aged and Disabled program, Medicaid, NJ [KidCare] FamilyCare, General Assistance, SSI, or New Jersey Unemployment Assistance.

2. through 3. (No change.)

(d) Upon receipt of the application, together with the executed release and the appropriate fee, the Department shall immediately assign the appeal to an IURO meeting the requirements of N.J.A.C. 8:38A-5.

1. The Department shall not assign appeals submitted by or on behalf of individuals that the Department know are being made with respect to coverage by public or private employer self-funded arrangements.

2. The Department shall not assign appeals submitted by or on behalf of individuals that the Department knows are being made with respect to coverage under policies or contracts issued or delivered in a state other than New Jersey.

3. The Department shall not assign appeals submitted by or on behalf of individuals that the Department knows are being made with respect to coverage under Medicare, Medicare+Choice or Medicare Advantage policies or contracts.

(e) Upon receipt of the application, the IURO shall conduct a preliminary review of the application and accept it for processing if it determines that:

1. The individual was [or is] a covered person of the carrier specified on the date of service at issue, or on the date on which the service request at issue was made;

2. through 4. (No change.)

(f) through (g) (No change.)

(h) The IURO shall conduct its initial full review through a registered professional nurse or licensed physician [licensed to practice in New Jersey] to determine what specialist(s) should be reviewing the case, and, when necessary, shall refer all cases for review to a consultant physician in the specialty or area of practice that generally would manage the type of treatment that is the subject of the appeal[, but shall not render a final recommendation except with the approval of the IURO's medical director.]

1. No reviewer shall have had any prior involvement with the appeal under review.

2. All reviewer determinations shall be subject to the approval of the medical director of the IURO.

(i) The IURO shall complete its review and issue its [recommendation] decision in writing as soon as possible consistent with the medical exigencies of the case, but in no instance later than 30 business days following the date of receipt of the appeal application, unless additional review time is necessitated by circumstances beyond the control of the IURO.

1. through 2. (No change.)

(j) (No change.)

(k) The IURO shall set forth in its written [recommendation] decision whether the IURO has determined that the covered person was deprived of receipt of or benefits for medically necessary services otherwise covered under his or her contract or policy, and shall specify the services the covered person should receive or receive benefits therefore in the event that the IURO is overturning the carrier's adverse determination in whole or in part.

1. The IURO shall submit its [recommendation] decision to the covered person and his or her provider (if the provider assisted in filing the appeal with the covered person's consent), the carrier and the Department.

8:38A-3.7 Carrier action on the IURO decisions

(a) A carrier shall submit a written report to the covered person and his or her provider (if the provider assisted in filing the appeal), the Department and the IURO [of its intent to accept and implement or reject] describing how the carrier will implement the IURO's decision and recommendation(s) within [10] 5 business days [of] following the date that the carrier first receives the [recommendation] decision of the IURO.

1. (No change.)

2. [If the carrier rejects one or more of the recommendations of the IURO, the carrier shall specify in its written report every basis for which its has rejected a recommendation] To the extent that only payments remain

outstanding, the carrier shall resolve the outstanding payments within 15 days following receipt of the IURO's written determination, or shall comply with the requirements of N.J.A.C. 11:22-1 to the extent that the claims are submitted to the carrier only following issuance of the IURO's written determination.

3. Upon request, the carrier shall provide proof to the Department that the carrier complied with or is in compliance with the decision of the IURO.

(b) A carrier that [elects to accept and implement] implements one or more of the recommendations of an IURO shall not be liable in any action for damages to any person for any action taken to implement a recommendation[, notwithstanding that the carrier may elect to implement only a portion of the IURO's recommendations].

8:38A-3.8 Continuous quality improvement

(a) (No change.)

(b) No later than June 30, 2000, a carrier shall set forth its system for its CQI program in a plan reviewable upon request by the Department specifying the following:

1. through 7. (No change.)

8. A system of monitoring satisfaction of covered persons[; and]

9. A system for evaluation of the effectiveness of the CQI program[.] ; and

10. A description of the criteria and methods to be used in utilization control, particularly the criteria for determining over- and under-utilization.

(c) through (e) (No change.)

[(f) The Department's review of a carrier's health benefits plan that has been approved as a selective contracting arrangement is not intended to be duplicative of, but complementary to, the review of the carrier's utilization review program and quality assurance program made pursuant to N.J.A.C. 11:4-37.4(c)11, 12 and 13.]

8:38A-4.2 Disclosures to covered persons

(a) through (d) (No change.)

(e) [In those instances in which covered persons are required to select a primary care provider in accordance with the terms of the managed care plan, regardless of whether the primary care provider in any way controls access to services in a gatekeeper system, the carrier shall provide written notification to covered persons of the termination of their primary care provider from the network at least 30 days prior to the termination date.

1. The carrier is not required to provide 30 days prior written notice in those instances in which the termination is for breach of contract, or the opinion of the carrier's medical director is that the primary care provider represents an imminent danger to an individual patient or the public health, safety or welfare, or there is a determination of fraud.

2. In the event that the carrier does not provide 30 days prior written notice pursuant to (e)1 above, the carrier shall provide written notice to the covered person as expeditiously as possible, and in no event later than 30 days following the date of termination] In addition to (a) through (d) above, the carrier shall provide statements to covered persons in a handbook or certificate no later than the effective date of coverage, setting forth the following information:

1. The right of the covered person to choose a primary care provider participating in the carrier's network, subject to each primary care provider's availability to accept new patients;

2. The right of the covered person to choose appropriate specialists from among participating providers in the carrier's network following an authorized referral, subject to each specialist's availability to accept new patients;

3. The right of the covered person to obtain through the carrier assistance and referral to participating providers with experience in treatment of patients with chronic disabilities, and to appropriate specialists in the carrier's network for treatment of acute conditions, including referral to providers and specialists outside of the carrier's network when providers are not available within a reasonable period of time within the network consistent with the medical exigencies of the covered person's situation, subject to the provision of in-network benefits under such circumstances; and

4. The right of the covered person to be free from balance billing by participating providers when the covered person is entitled to in-network benefits for medically necessary services that were authorized or covered by the carrier pursuant to the terms of the covered person's health benefits plan, except as permitted or required for copayments, coinsurance and deductibles by contract.

(f) (No change.)

8:38A-4.5 Designation of a medical director

(a) through (b) (No change.)

(c) In addition to (b) above, the medical director shall be responsible for:

1. through 3. (No change.)

4. Establishing and overseeing a provider credentialing and participation committee or committees [to perform the following functions:

i. Establishment of a mechanism for ensuring review of provider credentials;

ii. Delineation of qualifications of participating providers;

iii. Review of credentials of physicians and other providers who do not meet the carrier's standard credentialing requirements; and

iv. Establishment of a mechanism for:

(1) Verifying provider credentials, recertifications, and performance reviews; and

(2) Obtaining information regarding any disciplinary action against a provider available from the New Jersey Board of Medical Examiners or any other state licensing board applicable to the provider, or from the Federal Clearinghouse established pursuant to the Health Care Quality Improvement Act, Pub. L. 99-660 (42 U.S.C. §§ 1101 et seq.)];

5. through 7. (No change.)

(d) The carrier shall be able to demonstrate, upon the Department's request, the active oversight by the medical director (or his or her designee, when appropriate), of those areas under his or her responsibility through written documentation, including committee meeting minutes, and affirmative review of policies, procedures and protocols.

8:38A-4.5A Credentialing committee

(a) The designated medical director shall participate in the credentialing committee.

(b) The committee shall be responsible for oversight of the mechanisms designed to ensure that provider credentials are verified and reviewed periodically, including the credentials of all participating providers and providers engaged in the utilization management program.

1. The committee shall establish the standards for the credentialing process, including the timeframes for recredentialing and policies and procedures for addressing updates of information obtained outside of the recredentialing cycle.

2. The mechanisms shall include a system for verification of a provider's credentials, recertification, performance reviews and obtaining information about any disciplinary action against the provider available from the New Jersey Board of Medical Examiners or any other state licensing board applicable to the provider, or the Federal Clearinghouse established pursuant to the Health Care Quality Improvement Act, P.L. 99-660 (42 U.S.C. § 1101 et seq.)

3. The system shall be in compliance with N.J.A.C. 8:38C-1.

4. The system shall be designed to provide information to, and obtain information from the continuous quality improvement program, as well as receive and act upon information from the covered person and provider complaints systems directly.

(c) The committee shall be responsible for establishing and delineating the qualifications for all participating providers.

(d) The committee shall be responsible for determining which physicians, if any, qualify as PCPs despite not meeting the requirements of N.J.A.C. 8:38A-4.10(f).

8:38A-4.6 Complaint system

(a) A carrier shall establish and maintain a system for the presentation and resolution of complaints brought by covered persons regarding the carrier's contracts or policies, choice and accessibility of network providers, and network adequacy, incorporating to the satisfaction of the Department at least the following components:

1. (No change.)

2. A system to record and document the status of all complaints, which shall be maintained for at least three years following resolution of the complaint;

3. (No change.)

4. Establishment of a specified response time for resolution of complaints, not to exceed 30 days from receipt of the complaint by the carrier.

i. (No change.)

5. through 7. (No change.)

8. A mechanism for notifying covered persons and providers in writing that they may contact the Department or the Department of Banking and Insurance, depending upon the issue, if dissatisfied with the resolution reached through the carrier's complaint system.

(b) Every carrier shall establish and maintain a system to provide for the presentation to and resolution by the carrier of complaints brought by providers, which shall be a part of the carrier's CQI program, and shall, at a minimum, incorporate, to the satisfaction of the Department, the following components:

1. There shall be a policy and procedure for providing notice to participating providers about the opportunity to make inquiry or complaint regarding one or more aspects of the carrier's operations, including instructions on how to submit both verbal and written complaints.

2. There shall be a policy and procedure for logging, tracking and maintaining a record of the receipt, handling and resolution of complaints,

and maintaining such records for at least three years following resolution of the complaint.

3. There shall be a policy and procedure for handling complaints, including:

i. A reasonable timeframe for complaint resolution, not to exceed 30 days following receipt of the complaint, unless the carrier has obtained agreement from the provider to an extension of the stated time period, which in no instance shall be more than 60 days from the date of receipt of the complaint.

ii. Follow-up action regarding the complaint, including a mechanism for notifying providers of the resolution of the complaint, and entering the complaint into the CQI program when the complaint is valid and involves issues being monitored by the CQI program.

(c) In addition to the complaint [process] processes delineated in (a) and (b) above, every carrier shall establish and maintain a system for the presentation and resolution of appeals brought by covered persons or by providers acting on behalf of a covered person with the covered person's specific consent, with respect to utilization management determinations made by the carrier, which appeals process shall comply with [all] N.J.A.C. 8:38A-3.5.

(d) through (e) (No change.)

(f) Every carrier shall be responsive to Department inquiries regarding complaints presented to the Department by various constituencies, and cooperative with Department staff in bringing resolution to the complaint within 15

days of receipt by the carrier, or any greater or shorter period as specified by the Department in its request.

8:38A-4.7 [Provider] Health care professional application for participation

(a) No later than August 29, 2000, a carrier shall establish a committee to review applications submitted by licensed [providers] health care professionals to become members of the carrier's network.

1. The carrier may, but is not required to, combine the functions of this committee with another committee, such as the credentialing committee, so long as when performing its application review functions, the committee meets the requirements of this section.

2. [The carrier shall not be required to combine the functions of this review committee with the functions of any committee whose function includes credentialing standards.

3.] The committee shall be composed of no less than three people.

4. At least one of the committee members reviewing a specific application shall be a health care [providers] professional with knowledge in the applicant [provider's] health care professional's scope of professional practice.

(b) The committee shall complete its review of a complete application within no more than 90 days [of] after receipt of the complete application.

1. (No change.)

2. The committee shall provide notice of its action on a complete application to the [provider] health care professional in writing.

3. (No change.)

(c) (No change.)

(d) [The carrier may establish its own application forms, but if it does not elect to establish its own form, the carrier shall make available, upon request, a written notice of the information it requires to be submitted to determine an application is complete.] A carrier shall not establish a participation application form separate from its credentialing form(s), and shall otherwise comply with the requirements of N.J.A.C. 8:38C-1.

(e) (No change.)

8:38A-4.8 Termination of providers from a network

(a) A carrier shall give a health care professional written notice at least 90-days prior to termination of the provider's contract, specifying the health care professional's right to a hearing before a panel appointed by the carrier.

1. The carrier shall set forth in writing the reasons for the termination [if requested by the health care professional and]],within no more than 15 days following receipt the written notice of termination, if the reason is not otherwise stated in the written notice of termination.

2. The carrier shall send all notices related to the termination, including the reasons for the termination, if sent separately, via certified mail to the last known address of record on file with the carrier, and to each address of record of a health care professional in the event the health care professional has multiple existing or alternative addresses of record with the carrier.

(b) (No change.)

(c) With respect to contracts and policies in which covered persons are required to select a PCP and there is a gatekeeper system, and whenever a covered person is currently receiving a course of treatment from a participating provider, carriers shall provide written notification to each covered person within at least 30 business days prior to the termination or withdrawal from the carrier's provider network of a covered person's PCP and any other physician or provider from which the covered person is currently receiving a course of treatment.

1. through 2. (No change.)

3. The carrier shall honor referrals made by a terminated PCP if the referral is made prior to the date of the PCP's termination, or after the date of termination if continued care is required in accordance with (d) below[)].

4. Except where notice is waived, the carrier's written notice to covered persons regarding terminated health care professionals shall include statements detailing the continuity of care period requirements of the terminated health care professional(s) as outlined in (d) below, including:

i. The right of the covered person to determine to continue seeing the health care professional for medically necessary services under the same terms and conditions during the continuity of care period as applied prior to the continuity of care period;

ii. The right of the health care professional to refer the covered person or seek preauthorization or precertification for medically necessary hospital services without regard to the participation status of the

hospital, and without any penalty accruing to the health care professional or the covered person;

iii. The beginning and end date of the continuity of care period; and

iv. An explanation as to whom covered persons may contact to obtain more information regarding the termination and continuity of care period and the covered person's rights to continuity of care.

5. Notices to covered persons may encourage them to transition their care to another health care professional within the carrier's network prior to the end of the continuity of care period; however, notices shall not be worded so as to discourage covered persons from continuing to seek services from a terminated health care professional during the continuity of care period.

(d) (No change.)

(e) The carrier shall send a notice to terminated health care professionals, at least 30 days prior to the effective date of the termination, reminding them of their continuity of care period obligations under contract and law.

(f) The carrier shall establish policies regarding the termination of providers other than health care professionals.

[(f)] (g) The carrier shall establish a policy and procedure, reviewable upon request by the Department or the Department of Banking and Insurance, addressing the following:

1. through 2. (No change.)

8:38A-4.10 Network adequacy

(a) [Except with respect to any selective contracting arrangement approved on or before May 1, 2000 pursuant to N.J.A.C. 11:4-37, a] A carrier shall maintain an adequate network, as set forth in (b) below, of PCPs, specialists and other ancillary providers to assure that covered persons are able to access services in-network and take full advantage of the in-network benefits levels when the policy or contract specifies that there is a differential between the in-network and out-of-network benefits levels for one or more covered services, or the policy or contract is subject to a gatekeeper system.

1. through 2. (No change.)

3. Carriers shall in no way be relieved of the obligation to comply with network adequacy requirements on the basis that covered persons may receive benefits for covered services rendered by out-of-network providers.

i. Carriers shall provide assistance upon a covered person's request and help the covered person in obtaining medically necessary covered services from appropriate participating providers, and the carrier shall refer the covered person to nonparticipating providers, with the covered person being subject to in-network cost-sharing requirements, if the carrier's network does not have an appropriate participating provider available within a reasonable amount of time consistent with the medical exigencies of the covered person's condition.

(b) The carrier shall meet the following requirements for network adequacy:

1. The carrier shall have in its network available for every age group that the carrier expects to enroll or has enrolled a sufficient number of physicians to assure that at least two physicians eligible as PCPs are within 10 miles or 30 minutes driving time or public transit time (if available), whichever is less, of 90 percent of the carrier's covered persons. (For example, a network for a service area shall not be considered acceptable if there are 100 PCPs within acceptable geographic limits of 90 percent of the enrolled population accepting patients over the age of 18 but none accepting patients under the age of 18 if the carrier's enrollment includes or is projected to include members both over and under the age of 18.)

i. The carrier may provide that its network meets the standard by demonstrating where the age groups are located within a geographic area, if differing age groups are distributed variously across the service area relative to the primary care providers accepting new enrollment for the age groups; otherwise, the Department shall assume that the age groups are distributed similarly among the population in the service area.

ii. The carrier shall demonstrate sufficiency of network PCPs to meet the adult, pediatric and [primary] routine ob/gyn needs of the current and/or projected number of covered persons by assuming:

(1) through (2) (No change.)

[ii.] iii. To demonstrate PCP availability, a carrier shall verify that the PCP has committed to providing a specific number of hours for new patients that cumulatively add up to projected clinic hour needs of the projected number of covered persons over a 12-month period by county or service area.

(1) Carriers shall verify that the primary care provider's offices in each location for which a commitment of office hours has been made actually are facilities at which the primary care provider conducts patients visits, and not administrative offices only.

(2) The carrier shall demonstrate in writing the number of hours that each office location has committed to the carrier's covered persons.

(3) With respect to physicians that are ob/gyns, the carrier shall demonstrate in writing the number of hours that each office location has committed to the carrier's covered persons for the obstetrical services and gynecological services to be offered.

[iii.] iv. The carrier shall demonstrate that the network of PCPs is sufficient to ensure that:

(1) [If the carrier provides benefits for emergency services:

(A) Emergencies shall be triaged immediately through the PCP or by a hospital emergency department through medical screening or evaluation;

(B)] Urgent care shall be provided within 24 hours of notification of the PCP or carrier; [and

(C)] (2) [In both] There is immediate after-hour access to PCPs (which may be satisfied in accordance with N.J.A.C. 8:38A-4.10B), whether or not for emergent and urgent care[, PCPs shall be required to provide seven day, 24 hour access to triage services];

[(2)] (3) Routine appointments can be scheduled within at least two weeks; and

[(3)] (4) Routine physical exams can be scheduled within at least four months.

2. The carrier shall have a sufficient number of [the] medical specialists and subspecialists, as applicable to the services covered in-network, [to assure access] available to covered persons to provide medically necessary specialty care, including the provision of services on an in-network basis at in-network licensed health care facilities, such that a choice of medical specialists are accessible within 45 miles or one hour driving time, whichever is less, of 90 percent of covered persons within each county or approved sub-county service area.

i. (No change.)

ii. The carrier shall contract with a sufficient number of other health care professionals to assure that covered persons have a choice of providers to perform medically necessary covered services in-network, and consistent with the access requirements of (b)2 above.

3. For institutional providers, the carrier shall maintain an adequate number of contracts or other arrangements acceptable to the Department with a range of health care facilities sufficient to meet the [medical] health care and geographic accessibility needs of the carrier's covered persons and 12-month projected enrollment, [and maintain geographic accessibility of the services provided through institutional providers], subject to no less than the following:

i. The carrier shall have a contract or arrangement with at least one licensed general acute care hospital [with] such that there are licensed medical-surgical, pediatric, obstetrical and critical care beds and services in [any] each county or service area [that is] no greater than 20 miles or 30 minutes driving time, whichever is less, from 90 percent of covered persons within the county or service area, except in those instances in which no such licensed services are available.

ii. The carrier shall have a contract or arrangement with surgical facilities, including licensed general acute care hospitals, licensed ambulatory surgical facilities, and/or Medicare-certified physician surgical practices available in each county or service area that are no greater than 20 miles or 30 minutes driving time, whichever is less, from 90 percent of covered persons within the county or service area.

iii. The carrier shall have a contract or otherwise agree to cover medically necessary trauma services at a reasonable cost with all Level I or II trauma centers designated by the Department [pursuant to N.J.A.C. 8:33P], with the provision of benefits at the in-network level.

iv. The carrier shall have contracts or arrangements for the provision of the following specialized services at in-network benefit levels (if covered by one or more of the carrier's health benefits plans in network, and determined to be medically necessary), so that services will be available within 45 miles or 60 minutes average driving time, whichever is less, of 90 percent of covered persons within each county or service area:

(1) At least one hospital providing regional perinatal services;

(2) A hospital offering tertiary [pediatric] services <u>for adults, adolescents and children</u>;

(3) [In-patient] <u>Inpatient</u> psychiatric services for adults, adolescents and children;

(4) (No change.)

(5) Diagnostic <u>and interventional</u> cardiac catheterization services in a hospital;

(6) Specialty [out-patient] <u>outpatient</u> centers for HIV/AIDS, sickle cell disease, hemophilia, and cranio-facial and congenital anomalies; and

(7) (No change.)

v. The carrier shall have a contract or arrangement so that the following specialized services may be provided at in-network benefit levels (if covered by one or more of the carrier's health benefits plans in network, and determined to be medically necessary), so that services will be available within

20 miles or 30 minutes average driving time, whichever is less, of 90 percent of covered persons within each county or service area:

(1) [A] At least three licensed long-term care [facility] facilities with Medicare-certified skilled nursing beds;

(2) through (7) (No change.)

vi. through vii. (No change.)

viii. The carrier shall have a contract or other arrangement acceptable to the Department assuring access on an in-network basis to at least one hospital designated for long term acute care services in the southern, central and northern regions of the State, regardless of the carrier's approved geographic service area.

(c) (No change.)

(d) In any county or approved service area in which 20 percent or more of a carrier's projected or actual number of covered persons must rely upon public transportation to access health care services, as documented by U.S. Census Data, the carrier shall demonstrate that its network meets the travel time requirements in (b) above, and shall base the driving times [set forth in the specifications of (b) above shall be based] upon average transit time using public transportation[, and the carrier shall demonstrate how it will meet the requirements in its application].

(e) [The carrier shall not deny any registered pharmacy or pharmacist the right to participate as a preferred provider if the carrier provides pharmacy

services, prescription drugs, or a prescription drug plan and the pharmacy meets the carrier's standards for participation.

1. Carriers shall comply with rules, if any, promulgated by the Department of Banking and Insurance applicable to the type of carrier.] In order to demonstrate that the carrier's covered persons have access to the services of the health care providers set forth in (b)2 and 3 above, the carrier shall verify that the providers are available and have the capacity to accept new patients and are committed to allocating resources to new patients of the carrier that cumulatively add up to the carrier's projected hourly or service needs of its projected enrollment over a 12-month period by county or service area.

(f) Those providers qualified to function as PCPs may include:

1. (No change.)

2. A licensed physician who does not meet the standards of [(e)] (f)1 above, but who has been evaluated by the carrier's committee charged with setting standards for and reviewing provider credentialing under the direction of the carrier's medical director, and is found by that committee to demonstrate through training, education and experience, equivalent expertise in primary care;

3. [Nurse practitioners/clinical nurse specialists certified by the State Board of Nursing in accordance with N.J.S.A. 45:11-45 et seq. in advance practice categories comparable to family practice, internal medicine, general practice, obstetrics and gynecology or pediatrics, and in hospitals or other facilities;

4. Physician assistants licensed by the New Jersey Board of Medical Examiners;

5.] Certified nurse midwives registered by the New Jersey Board of Medical Examiners; and

[6.] 4. At the discretion of the carrier, appropriate, licensed medical specialists for specified individual covered persons or patient groups who, due to health status or chronic illness, would benefit from medical care management by such a medical specialist.

8:38A-4.10A After-hour access to physician services

(a) Carriers shall assure that covered persons have access to physician services, including psychiatric care, provided outside of the physician's normal office hours.

(b) Participating physicians, including psychiatrists, shall be accessible at least by telephone 24 hours a day, seven days a week to address after-hours health care needs of covered persons, and to refer covered persons for emergency department services only as appropriate to the covered person's symptoms.

1. Carriers may arrange with their participating PCPs to have after hour calls routed to a triage service in order to satisfy the requirement that physician services be available round the clock daily, so long as the triage service is local or regional in nature, has physician consultation capability, and

referral of covered persons to emergency department services are limited to situations appropriate to the covered person's symptoms;

2. Carriers may arrange with their participating physicians to have back-up physicians available to take after-hour calls in order to satisfy the requirement that physician services be available round the clock daily, so long as the back-up physician is subject to the same medical practice and contractual standards as apply to the participating physician.

(c) Nothing herein shall be construed to allow carriers to deny claims for services rendered in an emergency department solely because the covered person did not obtain prior approval of or referral to emergency services, nor to deny payment of a medical screening performed in accordance with N.J.A.C. 8:43G-12.7 and/or 42 C.F.R. 489.20.

8:38A-4.11 Utilization management program

(a) (No change.)

(b) In addition to (a) above, the carrier shall comply with the following:

1. The carrier shall develop its UM criteria and protocols with involvement from its participating providers in accordance with N.J.A.C. 8:38A-4.14; [and]

2. [For contracts or policies in which emergency and/or urgent care services are covered, and preauthorization may be required, the] The carrier shall establish a mechanism to ensure that covered persons have immediate access to their PCP or his or her authorized on-call back-up provider, and that all

covered persons have access to a registered nurse or physician on the UM staff to respond to inquiries concerning emergency or urgent care seven days per week, 24 hours per day; and

3. The carrier shall have policies and procedures for implementing the collection, analysis and dissemination of outcome and process measures within the utilization management and quality improvement programs.

4. A carrier using a gatekeeper system shall have a registered professional nurse or physician on the carrier's utilization management staff available at all times to respond to inquiries from members concerning emergency or urgent care in the event that a covered person is unable to obtain a response from his or her PCP or the PCP's back-up provider.

i. Nothing herein shall be construed to allow carriers to deny claims for services rendered in an emergency department solely because the covered person did not obtain prior approval of or referral to emergency services, nor to deny payment of a medical screening performed in accordance with N.J.A.C. 8:43G-12.7 and/or 42 C.F.R. 489.20.

ii. The carrier shall provide notice to covered persons of the availability of access to the carrier's utilization management staff for both routine utilization-related inquiries, and for emergency and urgent care situations when covered persons are unable to contact their PCP's offices, including provision of the telephone numbers and hours for contact, when applicable.

iii. The carrier may satisfy the notice requirement of 4ii above by listing the telephone number(s) for medical necessity inquiries on identification cards provided to covered persons.

8:38A-4.13 Continuous quality improvement

(a) (No change.)

(b) A carrier shall have performed and shall submit to the Department, by May 1, 2002 or entrance of the carrier into the managed care plan market, and every 36 months thereafter, documentation of its most recent external quality audit performed by an external quality audit review organization approved by the Department.

1. The carrier shall submit the [documentation] report of the external quality review organization to the Department within 60 days of its receipt in final form by the external quality review organization.

2. (No change.)

3. Currently-approved external quality review organizations include:

i. The National Committee for Quality Assurance (NCQA);

ii. The Utilization Review Accreditation Commission (URAC);

iii. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO); and

iv. PRO NJ, The Healthcare Quality Improvement Organization of New Jersey, Inc. (PRO).

4. The Department may consider approval of other external quality review organizations upon request based upon the subjects to be audited, and the criteria and protocols for the audit.

(c) The [documentation] external quality review organization's report shall describe in detail the carrier's conformance to the standards of the external quality review organization, other standard-setting bodies for carriers of the category to which the carrier belongs, and/or the rules of this State applicable to the carrier and its managed care plans.

1. (No change.)

(d) (No change.)

[(e) The Department shall establish a Healthcare Data Committee (HeDaC) to assist the Department in developing a performance measurement and assessment system for monitoring the quality of care provided to covered persons as described in N.J.A.C. 8:38A-3.8, the quality of care provided to the covered persons of carriers subject to this subchapter, and the quality of care provided to covered person of carriers.

1. The HeDaC shall include no more than 15 and no less than 12 covered person who shall be appointed by, and serve at the pleasure of, the Commissioner. The covered person shall include providers, consumers, at least four insurer representatives, no more than two carrier representatives, and two other persons representing the interests of carriers. In addition to the above, a

representative of the New Jersey State Health Benefits Commission and the Departments of Banking and Insurance and Human Services shall serve as additional ex-officio covered person. The HeDaC shall be chaired by the Commissioner or his or her designee. Additional experts may be invited to participate on an invitational ad hoc basis as needed.

2. The HeDaC shall advise the Commissioner on the development of a uniform data reporting system to obtain reliable, standardized and comparable information from all carriers subject to this subchapter, and carriers. In the process of developing this system, the HeDaC shall address the following:

i. The relevance, validity and reliability of each measure selected to be an indicator of performance;

ii. The protection of confidentiality of patient-specific information;

iii. The cost and difficulty of data collection;

iv. The measures to reduce duplicative reporting of information to state agencies; and

v. The public release of data in formats useful to purchasers and/or consumers.

3. The HeDaC shall advise the Commissioner as to the data reporting established pursuant to (e)2 above that should be applicable to carriers that are subject to N.J.A.C. 8:38A-3.8, if any, and shall advise the Commissioner as to the appropriate data reporting to obtain from such carriers.]

8:38A-4.14 Provider input on protocols

(a) A carrier shall develop written clinical criteria and protocols and shall base its UM determinations upon such clinical criteria and protocols.

1. The carrier shall develop its clinical criteria and protocols with the input of practicing physicians and other health care providers within the carrier's New Jersey, regional or national network.

2. (No change.)

(b) through (c) (No change.)

[(d) Notwithstanding (c) above, a carrier's internal or proprietary quantitative thresholds for UM shall be confidential, and shall not be required to be released pursuant to (c) above.]

8:38A-4.15 [Minimum standards for provider contracts] Provider agreements: compliance generally

[(a) Both primary contractor and secondary contractor agreements shall be consistent with laws regarding confidentiality of information and shall not be so worded that compliance with the terms of the contract would cause any health care provider to violate his or her professional licensing standards, including, but not limited to, N.J.S.A. 45:14B-31 et seq., and shall comply with the standards of (b) through (e) below.

(b) In addition to complying with N.J.A.C. 11:4-37, all provider contracts shall specify:

1. The term of the contract and reasons for which the contract may be terminated by one or more parties to the contract, including the procedures for notice and effectuation of such termination, and opportunities, if any to cure any deficiencies prior to termination, subject to the following:

i. Provisions regarding notice of termination shall specify that if the contract is terminated prior to the contract's renewal date, the carrier shall give the provider at least 90 days prior written notice; and, that in the event of such a termination, the provider has a right to request a hearing following such notice except in enumerated circumstances consistent with N.J.A.C. 8:38A-4.9;

ii. Provisions regarding contents of the notice of termination to be provided shall specify that the notice shall contain a statement as to the right of the provider to obtain a reason for the termination in writing from the carrier if the reason is not otherwise stated in the notice; the right of the provider to request a hearing, and any exceptions to that right; and, the procedures for exercising either right;

iii. Provisions regarding the hearing shall set forth the procedures for requesting a hearing, and otherwise shall be consistent with the standards set forth at N.J.A.C. 8:38A-4.9;

iv. Provisions regarding the hearing shall include a statement that a provider's participation in the hearing process shall not be deemed to be an abrogation of the provider's legal rights; and

v. Provisions regarding the right of the provider to request from the carrier the reasons for the termination shall specify the procedure for the provider to make the request, and that the carrier's reason in response to the request shall be in writing;

2. That no provider may be terminated or penalized because of filing a complaint or appeal as permitted by these rules;

3. That no provider may be terminated or penalized for acting as an advocate for the patient in seeking appropriate, medically necessary health services;

4. That a provider shall continue to provide services to covered persons at the contract price following termination of the contract, in accordance with N.J.A.C. 8:38A-4.8;

5. The method of reimbursement, including the method, events and timing of application of any penalties, bonuses or other types of compensation arrangements, subject to the following:

i. The contract shall not provide financial incentives to the provider for the withholding of covered health care services that are medically necessary, but this shall not prohibit or limit the use of capitation arrangements between the carrier and provider;

ii. To the extent that some portion of the provider compensation is tied to the occurrence of a pre-determined event, or the nonoccurrence of a pre- determined event, the event shall be clearly specified,

and the carrier shall include in its contracts a right of each provider to receive a periodic accounting (no less frequently than annually) of the funds held;

iii. The contract shall include a process whereby a provider may appeal a decision denying the provider additional compensation, in whole or in part, in accordance with any compensation arrangement tied to the occurrence or nonoccurrence of a pre-determined event; and

iv. Notwithstanding (a)5i above, capitation shall not be used as the sole method of reimbursement to providers who primarily provide supplies (for instance, prescription drugs or durable medical equipment) rather than services;

6. The services and/or supplies to be provided by the provider and for which benefits will be paid by the carrier;

7. That providers shall not discriminate in their treatment of the carrier's covered persons;

8. That providers shall comply with the carrier's utilization review program, and quality assurance program as applicable to the provider;

9. That patient information shall be kept confidential, but that the carrier and the provider shall engage in timely and appropriate communication of patient information, so that both the providers and the carrier may perform their respective duties efficiently and effectively for the benefit of the covered person;

10. The process for an internal provider complaint and grievance procedure to be used by participating providers, pursuant to N.J.A.C. 8:38A-4.6(b); and

11. That the provider shall have the right to communicate openly with a patient about all diagnostic testing and treatment options.

(c) In addition to (b) above, all primary care provider contracts and contracts with specialists shall specify:

1. The responsibility, if any, of the provider with respect to acquiring and maintaining hospital admission privileges; and

2. The mutual responsibility of the provider and carrier to assure 24 hour, seven-day a week emergency and urgent care services and benefits therefor to covered persons, as appropriate to the carrier's managed care plans, and the procedures to assure proper utilization of such coverage.

(d) In addition to (b) above, all health care facility contracts shall specify:

1. The responsibility of the health care facility to follow clear procedures for granting of admitting and attending privileges to physicians, and to notify the carrier when such procedures are no longer appropriate;

2. The admission authorization procedures for covered persons;

3. The procedures for notifying the carrier when covered persons present at emergency departments, if notice is necessary to assure payment of benefits (other than a screening fee); and

4. The procedures for billing and payment, schedules, and any negotiated arrangements.

(e) No contract with any provider shall impose obligations or responsibilities upon a provider which require the provider to violate the statutes

or rules governing licensure of that provider if the provider is to comply with the terms of the contract.

(f) The form(s) of the provider agreements, and any amendments thereto, shall be submitted to the Department for prior approval.

(g) Provider agreements in effect on May 1, 2000 that are not in compliance with the requirements of this subchapter shall be deemed withdrawn on May 1, 2001.]

(a) The following provider agreements shall comply with the requirements of N.J.A.C. 8:38A-4.15C through 15G:

1. Provider agreements entered into directly between the carrier and a health care provider, including agreements for the performance of health care services by those entities described at N.J.A.C. 8:38B-2.1(c)1, 3, 5 and 6; and

(b) Except as (a) above applies, provider agreements entered into between a carrier and a health care provider indirectly through one or more intervening parties shall comply with N.J.A.C. 8:38B-5.

8:38A-4.15A Management and service agreements: compliance generally

(a) All management and service agreements, other than those solely related to marketing and/or claims processing, shall be subject to the requirements of N.J.A.C. 8:38B-4.4 through 4.10, as applicable to the function(s) delegated, regardless of whether the secondary contractor is required to be certified or licensed as an ODS.

1. In all instances, cross-references at N.J.A.C. 8:38B-4 shall be to the provisions of N.J.A.C. 8:38A, not to N.J.A.C. 8:38.

(b) All service agreements related to the delegation of marketing or claims functions shall contain provisions consistent with the requirements of the rules of the Department of Banking and Insurance regulating marketing and claims handling respectively, including N.J.A.C. 11:2-11, 11:4-17 and 11:21-17 with respect to marketing, and N.J.A.C. 11:22-2 with respect to claims handling.

8:38A-4.15B Provider agreements, management agreements and service agreements: review and approval

(a) No carrier shall execute a contract or an amendment to a contract for a provider agreement, a management agreement or a service agreement unless the form thereof has been approved by the Department, except that the following shall not require the approval of the Department:

1. Amendments that are of a clerical nature;

2. Alternations to numbers, whether dollar amounts, enrollment amounts of the like, so long as there is no alteration of the methodologies for which the numbers were derived; and

3. The substitution of one variable provision for another, so long as both variable provisions were approved by the Department within the same form of management, service or provider agreement.

(b) Carriers shall submit all forms to the Department with a unique form number set forth on each page of the form, and shall set forth the form number on all amendments to be made to a form.

(c) Carriers shall submit new forms of provider agreements and amendments to previous forms of provider agreements to the Department for review and approval no less than 60 days prior to the date that the carrier intends to use the new or amended form(s).

(d) Forms of provider agreements and amendments thereto not affirmatively disapproved by the Department in writing within 60 days following receipt of the form at the Department shall be deemed approved if the carrier submits with each of its forms of provider agreements or amendments thereto, a completed Provider Agreement Certification Checklist, contained in the Appendix to Chapter 38 and which is available upon request made to the address set forth at N.J.A.C. 8:38A-2.2(a) or through the Department's website at http://www.state.nj.us/health/forms/index.shtml, as MC-8.

1. The certification shall be signed by an officer of the carrier attesting that the form is or continues to be in compliance with the requirements of this subchapter.

2. The Department may rely upon the certification in determining to approve a form of provider agreement, or amendments to forms of provider agreements, but in so doing does not waive its right or authority to review the forms or amendments to forms as the Department considers necessary or

appropriate for monitoring purposes, because of defect in a certification, or for other reasons.

3. If the form has been previously approved for use by an ODS, but the carrier elects to use a form number different from that used by the ODS in submission of the form, the carrier is strongly encouraged to provide information about the previous filing to the Department, along with the form number used by the ODS for the previous filing.

(e) New forms and amendments to previously approved forms of management and service agreements shall be submitted to the Department for review and approval prior to use of the form.

(f) If the Department disapproves a form, or amendment to a form of either a provider agreement, management agreement or a service agreement, the Department shall notify the carrier in writing, specifying the reason(s) for the disapproval.

(g) Failure of a carrier to respond to Department questions regarding a provider agreement, management agreement or a service agreement within 30 calendar days following the date of inquiry, the Department shall deem the form withdrawn without further notice.

8:38A-4.15C Provider agreements: general provisions

(a) All provider agreement forms shall contain:

1. A provision specifying that the contract and amendments thereto are subject to prior approval of the Department, and may not be effectuated without such approval.

i. The provision may state that the following types of amendments do not require prior approval of the Department:

(1) Amendments that are of a clerical nature;

(2) Amendments that alter numbers, be they dollar amounts, enrollment amounts or the like, without altering methodologies from which the numbers were derived; and

(3) Amendments that involve the substitution of one set of variable text for another set of variable text, if both sets of variable text were previously approved by the Department for the provider agreement form;

2. A provision specifying that any sections of the contract that conflict with State or Federal law are effectively amended to conform with the requirements of the State or Federal law;

3. A provision specifying the number of days or months required by all parties to the contract to provide notice of amendments to the contract.

i. The prior notice period required for a carrier to provide notice to a provider shall not be less than 30 calendar days.

ii. The provision shall include an exception to the required notice standards to accommodate more immediate changes that may be required by State or Federal law;

iii. The provision may include an exception to the required notice standards for changes that are not material, but only if the term "material" is defined in the contract.

4. A provision specifying the compensation methodology, including the fee schedule, between the carrier and the provider.

i. The provision shall not provide financial incentives to the provider for the withholding of covered health care services that are medically necessary, but this shall not prohibit or limit the use of capitated payment arrangements between a carrier and a provider.

ii. To the extent that some portion of the provider compensation is tied to the occurrence of a pre-determined event, or the non-occurrence of a pre-determined event, the event shall be clearly specified, and the carrier shall include in its contracts a right of each provider to receive a periodic accounting of the funds held, which shall be no less frequently than annually.

iii. The provision shall specify that a provider may appeal a decision denying the provider additional compensation to which the provider believes he or she is entitled under the terms of the provider agreement.

iv. Notwithstanding (a)4i above, capitation shall not be the sole method of reimbursement to providers that primarily provide supplies rather than services.

v. In no event shall the provision indicate that the compensation terms will be determined subsequent to the execution of the contract between the carrier and the provider.

5. A provision specifying that the provider's activities and records relevant to the provision of health care services may be monitored from time to time by the carrier or another contractor acting on behalf of the carrier to perform quality assurance and continuous quality improvement functions;

6. A provision explaining the quality assurance program with which the provider must comply.

i. The provision shall specify whether the quality assurance program is that of the carrier, or is that of a separate entity and is being adopted by the carrier.

ii. The provision shall specify the entity that is responsible for the day-to-day administration of the quality assurance program.

iii. The provision shall specify the entity with which the provider may lodge complaints regarding the quality assurance program, and otherwise provide information on how provider feedback regarding the operations of the carrier will be elicited;

7. A provision explaining the utilization management program with which the provider must comply.

i. The provision shall specify whether the utilization management program is that of the carrier or is that of a separate entity and is being adopted by the carrier.

ii. The provision shall explain what entity is responsible for the day-to-day operation of the utilization management program, how the provider is to comply with the UM standards, including the method for obtaining a UM decision and appealing UM decisions, and the right of the provider to have the name and telephone number of the physician appropriate to the services at issue, denying or limiting an admission, service, procedure or length of stay.

iii. The provision shall explain how providers may receive information regarding the UM protocols and any parameters that may be placed on the use of one or more protocols.

iv. The provision shall explain how participating providers may review and provide comment on the applicable protocols for the provider's practice area.

v. The provision shall explain that the provider has the right to rely upon the written or oral authorization of a service if made by the carrier or the entity identified as being responsible for the day-to-day operations of the UM program, and that the services will not be retroactively denied as not medically necessary except in cases where there was material misrepresentation of the facts to the carrier or the entity identified as being responsible for the day-to-day operations of the UM program, or fraud;

8. A provision explaining the rights and obligations of the provider when appealing a UM decision on behalf of a covered person, including the right to receive a written notice of the UM determination.

i. The provision shall be clear that the provider must obtain specific consent of the covered person after issuance of the adverse determination in order for the appeal to be reviewed in accordance with the Stage 1 and Stage 2 process as set forth at N.J.A.C. 8:38A-3.5, except as 29 C.F.R. 2560.503-1(b)(4) applies, and that no appeal is eligible for the Independent Health Care Appeals Program, established pursuant to N.J.S.A. 26:2S-11, until the covered person's specific consent to the appeal is obtained.

ii. The provision shall not limit the right of the provider to submit an appeal on behalf of the covered person to situations in which the covered person may be financially liable for the costs of the health care services;

9. A provision specifying that the contract is governed by New Jersey law;

10. A provision specifying the term of the contract;

i. Every provider agreement shall specify the date the contract is executed.

ii. The anniversary date of the contract shall be the execution date of the contract, if no anniversary date is otherwise specified;

11. A provision specifying termination and renewal rights and obligations of the parties with respect to termination and renewal;

12. A provision prohibiting providers from billing or otherwise pursuing payment from a carrier’s covered persons for the costs of services or supplies rendered in-network that are covered, or for which benefits are payable, under the covered person's health benefits plan, except for co-payments,

coinsurance or deductible amounts set forth in the health benefits plan, regardless of whether the provider agrees with the amount paid or to be paid, for the services or supplies rendered;

13. A provision establishing the obligation of the provider to be credentialed and otherwise eligible to participate in various programs (for example, Medicare or Medicaid), as appropriate.

i. The provision shall set forth the time periods for credentialing and recredentialing of providers, and the obligation of the provider to cooperate with the credentialing process;

14. A provision setting forth the requirement that medical malpractice insurance be maintained for health care professionals in an amount specified as a matter of the health care professional's license, or, if no amount is specified as a matter of license, in an amount not less than that required for physicians at N.J.S.A. 45:9-19.17 and rules promulgated pursuant thereto, as the statutes and rules may be amended from time to time;

15. A provision setting forth the health care services and supplies that the provider is to render to covered persons;

16. A provision specifying that providers shall have the right and obligation to communicate openly with all covered persons regarding diagnostic tests and treatment options;

17. A provision specifying that providers shall not be terminated or otherwise penalized because of complaints or appeals that the provider files on his or her own behalf, or on behalf of a covered person, or for otherwise acting as

an advocate for covered persons in seeking appropriate, medically necessary health care services covered under the covered person's health benefits plan;

18. A provision stating that the provider shall not discriminate in his or her treatment of a carrier’s covered persons.

i. The provision may permit providers to limit the total number of a carrier’s covered persons that the provider treats, so long as the standards for the limitations do not result in unfair discrimination and are set forth clearly in the provider agreement.

ii. The provision may permit the provider to limit the carrier’s products for which the provider will be considered a participating provider, so long as the standards for the limitations are set forth clearly in the provider agreement;

19. A provision setting forth the procedures for submitting and handling of claims, including any penalties that may result in the event that claims are not submitted timely, the standards for determining whether submission of a claim has been timely, and the process for providers to dispute the handling or payment of claims.

i. Provisions addressing claims handling shall be consistent with P.L. 1999, c.154 (Health Information Technology Act) as well as P.L. 1999, c.155, and rules promulgated pursuant thereto, including N.J.A.C. 11:22-1, and amendments to those statutes and rules as may occur from time to time.

ii. The provision shall specify how interest for late payment of claims shall be remitted to the provider, but in no instance shall the provision

obligate the provider to request payment of the interest before the interest will be paid;

20. A provision explaining how the provider may submit and seek resolution of complaints and grievances, separate and apart from submitting complaints and grievances on behalf of a covered person, and complaints addressing compensation and claims issues.

i. The provision shall specify the time frames for resolving complaints and grievances, which shall not exceed 30 days following receipt of the complaint or grievance.

ii. The provision shall explain the right of the provider to submit complaints and grievances to the Department, the Department of Banking and Insurance or the Department of Human Services (Division of Medical and Health Services), depending upon the issue involved, if not satisfied with the resolution of the complaint or grievance through the internal provider complaint mechanism.

21. A provision setting forth the confidentiality requirements that may apply to various records, including medical records, that the parties may maintain pursuant to their contractual relationship.

(b) Every provider agreement form may contain:

1. A provision specifying that the provider and the carrier are independent contractors as permitted by statute, regulation and/or common law.

i. The provision may specify that the carrier and the provider have no employment, partnership, joint venture, or other explicit business

relationship, but shall not deny the existence of an agency relationship between the carrier and the provider;

2. A provision specifying that the provider and any contract holders or other third parties with which the carrier may contract (other than subscribers and covered persons) are independent contractors as permitted by statute, regulation and/or common law.

i. The provision may specify that the provider and third parties have no employment, partnership, joint venture or other explicit business relationship, but shall not deny the existence of an agency relationship between the provider and the carrier; and

3. Other provisions not specifically prohibited in accordance with this subchapter or other law.

(c) No provider agreement form shall contain:

1. A provision that establishes any limitation on the time period during which a provider may bring suit that is less than that set forth under the statutes of limitation established by law;

2. A provision that establishes a unilateral right of the carrier to amend the contract, or that otherwise requires a provider to abide by the amended terms of the contract during either a notice of termination period or a continuity of care period in the event that the provider elects to terminate the contract rather than accept the amendment.

i. The provision may allow for unilateral amendment if the amendment is required by State or Federal law;

3. A provision that states or can be interpreted to mean that the provider may not appeal a utilization management determination on behalf of a covered person with the covered person's specific consent, or otherwise limits the right of the provider to dispute a utilization management determination, except that reasonable procedural standards may be specified, including a time frame during which an appeal may be submitted, so long as the reasonable procedures are consistent with the requirements of N.J.A.C. 8:38A-3.5;

4. A provision that states or can be interpreted to mean that the provider can not dispute a reassignment or bundling of codes on a claim, or that the provider must accept any or all adjustments to a claim as payment in full when the adjustment is made as a result of the quality assurance, continuous quality improvement, utilization management, provider incentive, or similar such program;

5. A provision that states that payment to a provider with respect to a medically necessary health care service or supply will be denied if the service was not pre-certified or pre-authorized.

i. There may be a provision that allows payment to be reduced up to, but not exceeding, 50 percent of what would otherwise have been paid had pre-certification or pre-authorization been obtained for a medically necessary service, but only if the actual percentage reduction is set forth in the provider agreement;

6. A provision that states or may be interpreted to mean that a covered person lacks the ability to dispute whether a service is a covered service

or whether the person was a covered person of a carrier at the time that the service was rendered;

7. A provision that requires the provider to assure that it never charges the carrier a rate that is greater than the least amount charged to another entity with which the provider contracts for similar services, or any other "most-favored-nation" type of clause;

8. A provision that requires a provider to be responsible for the actions of a non-participating provider; or

9. A provision that imposes obligations or responsibilities upon a provider that requires the provider to violate statutes or rules governing his or her license, or otherwise violate laws governing the confidentiality of patient information, in order to comply with the terms of the contract.

i. In addition, the contract shall not contain a provision that is inconsistent with laws setting forth procedures for determining whether and how specific types of confidential information may be released, including N.J.S.A. 45:14B-31 et seq.

(d) Details of contract provisions more appropriately set forth in provider manuals may be set forth accordingly, so long as the contract includes statements that the information is set forth in the provider manuals, the provider manuals are readily available to health care providers, and the provider manuals are submitted to the Department for review and are approved prior to use.

8:38A-4.15D Provider agreements: termination and continuity of care standards for contracts with health care professionals

(a) Provider agreements shall specify the term of the contract, reasons for which the contract may be terminated by one or more parties to the contract, procedures for notice and effectuation of such termination, and opportunities, if any, to cure any deficiencies prior to termination.

(b) The provider agreement may specify that the contract may be terminated without cause, so long as non-cause termination is permitted by either party subject to reasonable prior notice and the terms of the provision otherwise comply with the remainder of this section.

(c) The contract shall specify that, when the health care professional's status as a participating provider in a carrier's network is being terminated, written notice shall be issued to the health care professional no less than 90 days prior to the date of termination, except that the 90-day prior notice requirement need not apply when the contract is being terminated upon its date of renewal, or upon its anniversary date, if no annual renewal date is specified, or is being terminated because of breach, alleged fraud, or because, in the opinion of the medical director of the carrier, if different, the health care professional presents an imminent danger to one or more covered persons, or the public health, safety or welfare.

1. The contract shall specify that the health care professional shall receive a written statement setting forth the reason(s) for the termination, and the procedures for obtaining such a written statement, in the event that the written

notice of termination does not include a statement setting forth the reason(s) for the termination.

(d) The contract shall specify that the health care professional shall have the right to request a hearing following a notice that the health care professional's status as a participating provider with a carrier is being terminated, except that the contract may specify that the right to a hearing does not apply when the termination occurs on the date of renewal of the contract, or upon the contract's anniversary date, if no annual renewal date is specified, or termination is based on breach or alleged fraud, or because, in the opinion of the medical director of the carrier the health care professional presents an imminent danger to one or more covered persons, or the public health, safety or welfare.

(e) The contract shall specify the procedures for requesting a hearing from a carrier when a health care professional is terminated from participation in the carrier's network, which shall be consistent with the requirements of N.J.A.C. 8:38-3.6.

(f) The contract shall specify that when a health care professional's status as a participating provider is terminated, regardless of the party initiating the termination, the health care professional, if a physician, shall remain obligated to provide services for covered persons in accordance with N.J.A.C. 8:38A-4.8(d).

(g) Notwithstanding (f) above, the contract may specify an exception to the requirement for the provider to continue to provide care, and for the carrier to pay for services rendered by the provider following the effective date of termination when the termination is based on breach or alleged fraud, or because, in the

opinion of the medical director of the carrier, the health care professional presents an imminent danger to one or more covered persons, or the public health, safety or welfare.

8:38A-4.15E Provider agreements: termination and continuity of care standards for provider agreements with hospitals and other health care providers that are not health care professionals

(a) Provider agreements shall specify the term of the contract, reasons for which the contract may be terminated by one or more parties to the contract, procedures for notice and effectuation of such termination, and opportunities, if any, to cure any deficiencies prior to termination.

(b) The provider agreement may specify that the contract may be terminated without cause, so long as non-cause termination is permitted by either party subject to reasonable prior notice.

(c) The contract may specify that if a hospital's status as a participating provider is terminated, regardless of who initiates the termination, or the reason for the termination, the hospital shall continue to abide by the terms of the contract for a period of time following the effective date of the termination.

8:38A-4.15F Provider agreements: additional standards applicable to contracts with primary care providers and specialists

(a) The contract shall specify the mutual responsibility of the provider and carrier to assure 24-hour, seven-day per week emergency and urgent care

coverage to covered person, and the procedures to assure proper utilization of such coverage.

(b) The contract shall specify the obligation, if any, of the provider to acquire and maintain hospital admitting privileges.

8:38A-4.15G Provider agreements: additional standards applicable to contracts with hospitals

(a) The contract shall specify the obligation of the facility to follow clear procedures for granting of admitting and attending privileges, and to notify the carrier when such procedures change.

1. If notification must be made to one or more separate entities under contract with the carrier, this shall be stated in the contract.

(b) The contract shall specify the admission authorization procedures for carriers.

(c) The contract shall specify the procedures for notifying the carrier when covered persons present at emergency rooms.

(d) The contract shall specify procedures for billing and payment, scheduled and negotiated arrangements.

8:38A-4.15H Transfer of risk

(a) No secondary contractor shall assume, nor shall any carrier cede to a secondary contractor, some or all of the financial risk associated with a health benefits plan, whether through compensation formula, stop loss insurance

requirements or other means, unless the secondary contractor is an authorized payor or a licensed ODS.

(b) Any person accepting a transfer of risk from a carrier when that person does not otherwise qualify for the transfer of such risk shall be in violation of this subchapter and shall be subject to penalty and fine by the Department of Banking and Insurance under the insurance laws of this state as an unauthorized insurer in accordance with N.J.S.A. 17:51-1 et seq., or 17B:33-1 et seq., as may be appropriate.

8:38A-4.16 Reporting of quality outcome measures and compensation arrangements

(a) Carriers shall comply with [the] reporting requirements as may be established by the [HeDaC, which shall be promulgated by the] Department [in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., which shall include], including independent consumer satisfaction survey results and an analysis of quality outcomes of health care services.

1. through 6. (No change.)

7. Carriers shall submit data [established by the HeDaC] and other information required by this subsection as the Department may request from time to time.

8. (No change.)

(b) Carriers shall comply with the requirements of N.J.A.C. 8:38-11.7, submitting the information in conjunction with their financial statements required to be filed annually on March 1.

1. For purposes of complying with this requirement, [carriers] a carrier shall submit information for all of its managed care plan business by line, separated by Medicaid (if any), Medicare (if any), Medicare supplement (if any) and non- Medicare business if the carrier has different compensation arrangements for these lines of business.

2. (No change.)

8:38A-4.18 Limited service health benefits plans and dental benefits plans

(a) Carriers authorized to offer policies and contracts that provide single or limited services, such as vision services, or dental benefits plans, that elect to offer their policies as managed care plans with a utilization management program shall comply with the provisions of N.J.A.C. 8:38A-4 as appropriate to the type of services covered under the policy or contract, and as (b) through (d) below apply.

1. Nothing herein shall be construed to apply to policies that are solely or primarily for the provision of benefits for pharmacy services.

2. Nothing herein shall be construed to apply to any benefit design offered or intended to be offered only as a rider to other health benefits plans.

(b) Carriers offering a policy or contract that does not provide any benefits for expenses or coverage of services rendered by a health care professional that is a physician or surgeon licensed pursuant to N.J.S.A. 45:9-1 et seq. shall not be required to designate a medical director pursuant to N.J.A.C. 8:38A-4.5, but shall be required to designate a health care professional licensed to perform the services that are covered under the policy or contract, or for which benefits are provided.

1. The designated health care professional shall be licensed to practice in New Jersey.

2. The designated health care professional shall be responsible for the functions set forth at N.J.A.C. 8:38A-3.3(b) and 4.5.

3. The carrier shall not be required to comply with N.J.A.C. 8:38A-4.5(b)3 or (d).

(c) The carrier may, but shall not be required, to comply with the provision of N.J.A.C. 8:38A-4.7(d), in whole or in part.

(d) If the limited service health benefits plan does not cover services that may be needed on an emergency or urgent care basis, the carrier shall not be required to comply with N.J.A.C. 8:38A-4.10A or 4.11(b)4.

(e) With respect to N.J.A.C. 8:38A-4.14, no carrier shall be required to develop its protocols applicable to the limited service health benefits plans and dental benefits plans with input from physicians or other health care providers whose services are not covered under the terms of the limited service health benefits plan or dental benefits plan.

1. Notwithstanding (d) above, if multiple health care provider disciplines may perform the services covered under the limited service health benefits plan or dental benefits plan within the scope of their respective practices, the carrier shall provide a mechanism for input into the development and review of protocols from all appropriate disciplines.

8:38A-5.1 General requirements

(a) The Department shall be responsible for the operation of the Independent Health Care Appeals Program.

1. The Department shall combine the Independent Health Care Appeals Program with the External Appeals program set forth under N.J.A.C. [8:38-8-7] 8:38-8.7, but, in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., may amend the standards set forth at N.J.A.C. 8:38-8.7 as necessary to make the appeal process more effective for covered persons insured through contracts or policies of carriers that are not HMOs.

2. through 3. (No change.)

(b) Carriers [who] that are the subject of an appeal through the Independent Health Care Appeals Program shall comply with the requirements of N.J.A.C. 8:38-8.7, with the term "HMO" being read to mean "carrier" and the term "member" being read to mean "covered person," and in addition, the carrier shall be responsible for paying the cost of the appeal.

1. The per case cost may be revised from time to time; a carrier shall be responsible to pay the per case cost that [is applicable on] exists upon the date that the preliminary review of the appeal is completed by the IURO.

2. The carrier shall submit payment to the IURO for the appeal no later than 30 days following the date that the IURO renders its [final recommendation] determination on the appeal in writing to the Department.

8:38A-5.2 [Department review of carrier actions on IURO recommendations] Reserved

[(a) The Department shall periodically review records of carrier reports submitted pursuant to N.J.A.C. 8:38A-3.7 to determine whether a carrier exhibits a pattern of noncompliance with the recommendations of an IURO as well as possible violations of patient rights or other applicable laws.

(b) If the Department determines that a carrier exhibits a pattern of noncompliance with the recommendations of an IURO, the Department shall review:

1. Whether the carrier's noncompliance is with a specific set of recommendations;

2. Whether the carrier's noncompliance is with a specific IURO (in the event more than one IURO participates in the Independent Health Care Appeals Program); and

3. The carrier's utilization management program, if any.

(c) If the Department determines that the carrier's utilization management program is not in compliance with the utilization management standards set forth at N.J.A.C. 8:38A-3.4 and 4.11, as applicable, or other relevant laws, the Department shall:

1. Notify the Department of Banking and Insurance of the violation; and

2. Take action(s) as deemed appropriate, in the discretion of the Commissioner, if any, pursuant to N.J.A.C. 8:38A-2.7.

(d) If the Department determines that the carrier is in violation of patient rights or other applicable regulations, the Department shall:

1. Notify the Department of Banking and Insurance of the violation; and

2. Take action(s) as deemed appropriate, in the discretion of the Commissioner, if any, pursuant to N.J.A.C. 8:38A-2.7.

(e) A pattern of noncompliance shall mean the occurrence of multiple incidents of refusal to follow the recommendations of the IURO, in whole or in part, within a 12 month period, when such recommendations require the carrier to provide services or benefits therefor to a covered person.]

APPENDIX

Exhibit 1

[New Jersey Department of Health and Senior Services

Office of Managed Care

PO Box 360

Trenton, NJ 08625-0360

AN EXPLANATION OF THE INDEPENDENT HEALTH CARE APPEAL PROCESS

A covered person, and any provider acting on behalf of a covered person with the covered person's consent, who is dissatisfied with the results of a carrier's internal appeal process shall have the right to pursue his or her appeal to an Independent Utilization Review Organization (IURO).

A covered person, or a provider acting on behalf of a covered person, MUST comply with the carrier's internal appeal process BEFORE an appeal can be made to an IURO.

An appeal to the IURO must be made within 60 days of the date a final decision was issued by the carrier. An IURO designated by the New Jersey Department of Health and Senior Services will determine whether the covered person was deprived of a medically necessary covered service, as a result of the

carrier's utilization management determination. The Department shall assign appeal requests to an approved IURO.

Preliminary Review:

Upon receipt of the request for appeal from the Department, the IURO will conduct a preliminary review of the appeal and accept it for processing if it determines that:

1. The individual was a covered person of the carrier at the time of the action on which the appeal is based;
2. The service which is the subject of the complaint or appeal reasonably appears to be a covered service under the benefits provided by contract to the covered person;
3. The covered person, or provider acting on behalf of the covered person, has completed the carrier's internal appeals process; and
4. The covered person, or provider acting on behalf of the covered person with the covered person's consent, has provided all information required by the IURO and Department to make the preliminary determination. This information includes the appeal form, a copy of any information provided by the carrier regarding its decision to deny, reduce or terminate the covered service, and a fully executed release to obtain any necessary medical records from the carrier and any other relevant health care provider.

The IURO will complete the preliminary review and notify the covered person and/or provider in writing as to whether the appeal has been accepted for processing and if not so accepted, the reasons therefor within 5 business days of receipt of the request.

Full Review of Appeal:

Upon acceptance of the appeal for processing, the IURO shall conduct a full review to determine whether, as a result of the carrier's utilization management determination, the covered person was deprived of medically necessary covered services. In reaching this determination the IURO shall take into consideration all information submitted by the parties and information deemed appropriate in the opinion of the IURO including: pertinent medical records, consulting physician reports and other documents submitted by the parties, any applicable, generally accepted practice guidelines developed by the Federal government, national or professional medical societies, boards and associations, and any applicable clinical protocols and/or practice guidelines developed by the carrier.

1. The IURO shall complete its review and issue its recommended decision as soon as possible in accordance with the medical exigencies of the case which, except as provided for herein, in no

event shall exceed 30 business days from receipt of all documentation necessary to complete the review.

2. The IURO may, however, extend its review for a reasonable period of time as may be necessary due to circumstances beyond its control. In such an event the IURO shall, prior to the conclusion of the 30 business day review period, provide written notice to the covered person and/or provider and to the carrier and Department setting forth the status of its review and the specific reasons for the delay.
3. The IURO will notify the Department when a carrier is non-compliant with requests for information and any other aspect of the external review process.
4. The IURO's written appeal decision must be sent to the covered person and/or provider, the carrier, and the Department of Health and Senior Services, Office of Managed Care, with a cover letter of transmittal signed by a responsible representative of the IURO. The written decision of the IURO must be signed by the medical director and shall indicate each and every basis of the IURO's recommendation.
5. [If the IURO determines that the covered person was deprived of medically necessary covered services, the IURO shall recommend in writing to the covered person and/or provider, the carrier and the

Department, the appropriate covered health care services the covered person should receive.

6. Within days the receipt of the determination of the IURO, the carrier shall submit a written report to the IURO, the covered person and/or provider, and the Department indicating whether it will accept and implement or reject the recommendations of the IURO. In the case of a rejection, the carrier shall specifically indicate in writing each and every basis for its rejection of the IURO's recommendation.
7. The IURO shall conduct emergent and urgent reviews, and will disclose the method and basis for rendering such decisions.

BEFORE YOU MAIL YOUR APPEAL:

__ Attach the filing fee of $25.00.

Make check or Money order payable to "New Jersey Department of Health and Senior Services." Send check or money order only; DO NOT SEND CASH (NOTE: The filing fee is reduced to $2.00 if there is financial hardship. You may show financial hardship by submitting evidence of participation in either Pharmaceutical Assistance to the Aged and Disabled, Medicaid, General Assistance, SSI, or New Jersey Unemployment Assistance.)

__ Attach a copy of the final written decision from the carrier.

__Attach a copy of Summary of Insurance Coverage from the covered person's Handbook, if available.

__ Sign the form.

__For providers filing on behalf of a covered person, have the covered person sign the form.

__ Attach a copy of all medical records and correspondence to be reviewed by the Independent Utilization Review Organization.

IMPORTANT: Send copies of any requested documents. Do not send original documents as they WILL NOT be returned.

IF YOU HAVE QUESTIONS, PLEASE CALL 1-609-633-0660.

DETACH AND RETAIN THIS PAGE.

IT CONTAINS IMPORTANT INFORMATION REGARDING THE IURO APPEAL PROCESS.

PHOTOCOPY AND RETAIN A COPY OF THE "REQUEST FOR CARRIER APPEAL BY INDEPENDENT UTILIZATION REVIEW ORGANIZATION (IURO)" FORM FOR YOUR RECORDS.] Reserved